"COMPARISION OF 25 MICROGRAM OF SUBLINGUAL MISOPROSTOL WITH 25 MICROGRAM OF VAGINAL MISOPROSTOL FOR INDUCTION OF LABOUR AT TERM"

Dissertation submitted to

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Tiruchirapalli, Tamil nadu, INDIA.

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The Tamilnadu Dr. M.G.R. Medical University,
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CERTIFICATE

This is to certify that the dissertation entitled, "**COMPARISION OF 25 MICROGRAM OF SUBLINGUAL MISOPROSTOL WITH 25 MICROGRAM OF VAGINAL MISOPROSTOL FOR INDUCTION OF LABOUR AT TERM**" is a bonafide work done by **Dr. N. Vanathi** at **K.A.P. Viswanathan Government medical college, Tiruchirapalli**. This dissertation is submitted to **The Tamilnadu Dr. M.G.R Medical University** in partial fulfillment of university rules and regulations for the award of M.D degree in Obstetrics and Gynaecology.

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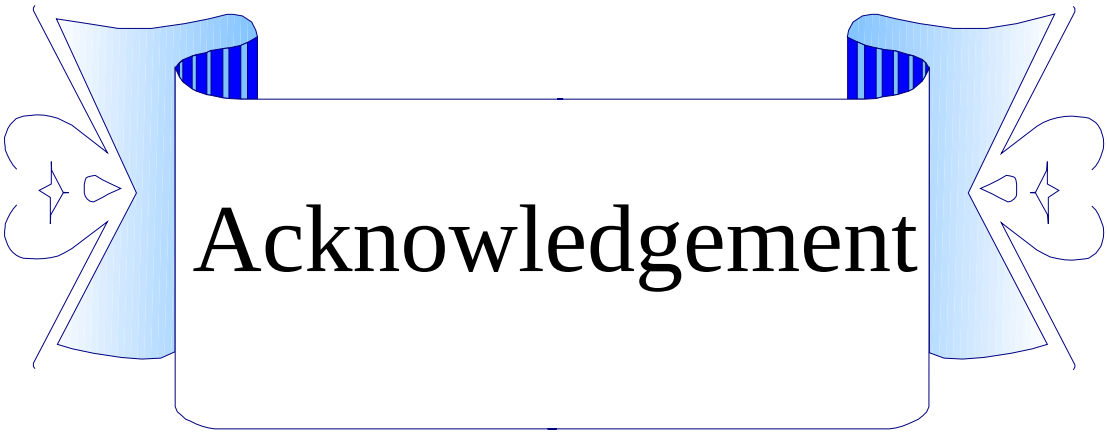
DECLARATION

I **Dr. N.VANATHI**, solemnly declare that the dissertation titled "**COMPARISION OF 25 MICROGRAM OF SUBLINGUAL MISOPROSTOL WITH 25 MICROGRAM OF VAGINAL MISOPROSTOL FOR INDUCTION OF LABOUR AT TERM**" is a bonafide work done by me at **K.A.P. Viswanathan government medical college, Tiruchirapalli**, during 2009 -2010 under the guidance and supervision of Prof**. Dr. PREMAVATHI PRABU ELANGO, MD., DGO.,** Professor and head of the department, Obstetrics and Gynaecology. This dissertation is submitted to **The Tamilnadu Dr. M.G.R Medical University**, in partial fulfillment of University rules and regulations for the award of M.D degree [Branch-II] in Obstetrics and Gynaecology.

Place: Tiruchirapalli

Date : **Dr. N. VANATHI**


Acknowledgement

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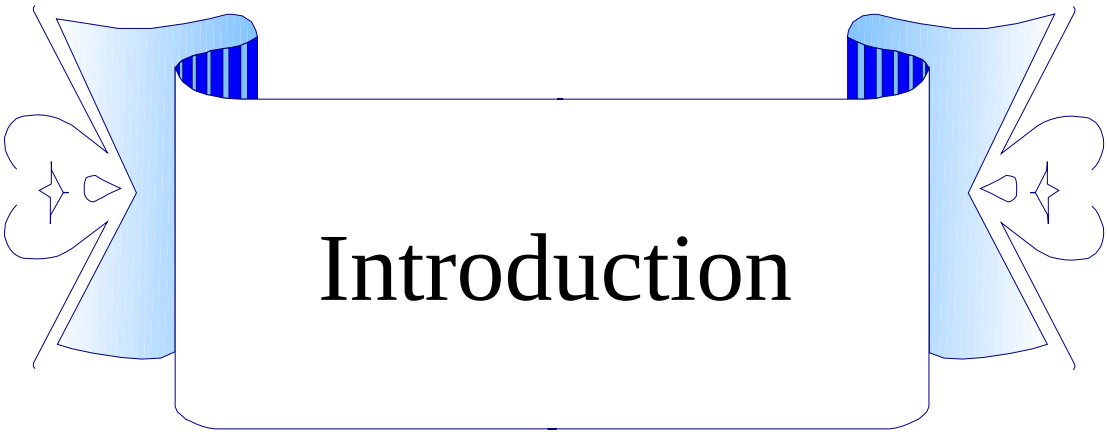
CONTENTS



Introduction

INTRODUCTION

The induction of labour in women with a live fetus at term remains a major challenge in modern obstetrics. Some centuries ago fetal death was the only indication for labour induction. Nowadays the rate of labour induction varies in different centers and is approximately more than 20%[1]. Despite a large body of literature on the subject, the optimal agent for this purpose has yet to be established.

Induction of labour includes natural, mechanical, surgical and pharmacological methods. Preference for particular method is not yet established completely and it depends on particular institute protocol. Pharmacological methods include oxytocin, misoprostol, mifepristone, dinoprostone etc. In the presence of unfavorable cervix induction is associated with increased risk of failed induction and caesarean section[2]. Hence to increase the likelihood of successful induction and decrease caesarean delivery risk cervical ripening is needed .The use of prostaglandin preparations with or without oxytocin infusion was widely recognised and accepted as a standard method for cervical ripening and labour induction[3]. However, natural prostaglandins are inconvenient to use, expensive and difficult to store, as they require refrigeration[4].

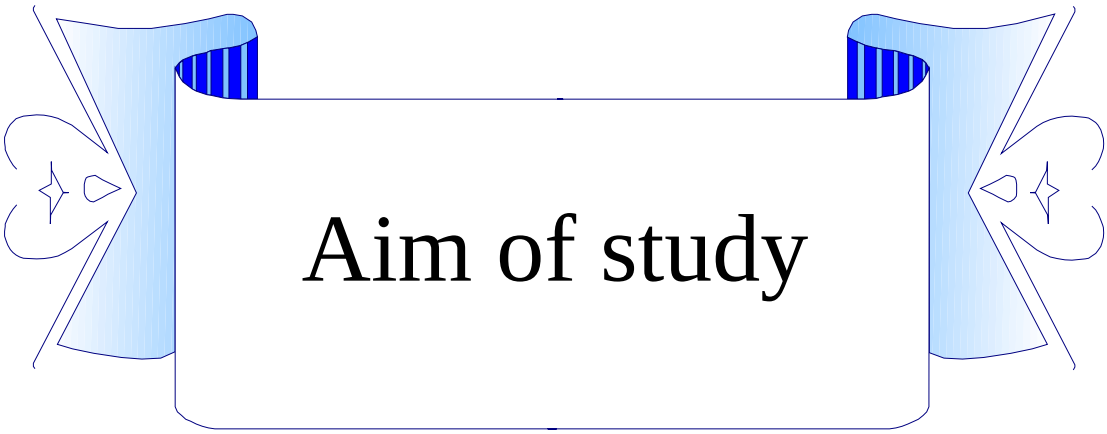
Misoprostol is a prostaglandin E1 analogue marketed since1988, as a gastric cytoprotective agent. It was first used to induce labour with a live fetus in 1991 and has gained wide spread acceptance for labour induction after several studies. Several routes of administration of misoprostol have been studied which had included oral, vaginal, rectal, buccal, and sublingual.[5]

Vaginal administration of misoprostol is a common route of practice for labour induction but it incurs a greater risk of undesirable adverse effects, such as uterine hyperstimulation syndrome, as well as having the inconvenience of vaginal administration[6]. To avoid this undesirable effect and inconvenience of vaginal administration, studies were conducted on oral route of misoprostol. Many clinical studies had found that vaginal administration was more effective than oral administration as systemic bioavailability after vaginal misoprostol was three times greater than the oral misoprostol.[7] To overcome the hyperstimulation syndrome and inconvenience in vaginal administration of vaginal misoprostol, lesser bioavailability in oral misoprostol, an alternative method was sought. Theoretically sublingual method of administration may be an alternative method as it combines the higher efficacy of vaginal route by avoiding gastrointestinal and hepatic metabolism and the lower hyperstimulation rates by avoiding a direct

effect on the cervix. Similar to the oral route, sublingual misoprostol has additional advantages, which include its easier administration, greater freedom of position after insertion and avoidance of repeated vaginal examinations[8].

The initial dose of vaginal misoprostol used was 50 micrograms every 2 hours up to a maximum total dose of 600 micrograms, resulting in vaginal delivery in 73% of cases and hyperstimulation syndrome in 3.6% of women.[9,10] Since then, lower doses have been proposed for the induction of labour in an attempt to reduce adverse effects[6,11]. After several studies, WHO and FIGO had recommended vaginal misoprostol dosage of 25 microgram every 4 hourly for maximum of 6 doses[12]. The utilization of sublingual misoprostol for labour induction with viable pregnancy had not been reported in the literature prior to 2001[8]. Pharmacokinetics study of different route of misoprostol had showed that sublingual route had greater bioavailability than vaginal route[5].

The objectives of this study were to determine the efficacy and safety of 25 microgram of sublingual misoprostol compared with 25 microgram of vaginal misoprostol for the induction of labour, in women with a live, term fetus and an unripe cervix.


Aim of study

AIM OF STUDY

To compare the efficacy and safety of 25 microgram of sublingual misoprostol with 25 microgram of vaginal misoprostol administered at 4-hour intervals for maximum of 6 doses for labour induction in term pregnancy with an unripe cervix.


Review of
Literature

REVIEW OF LITERATURE

INDUCTION OF LABOUR

Definition

Stimulation of uterine contraction before the spontaneous onset of labour, anytime after fetal viability, with or without rupture membranes, for the purpose of achieving vaginal delivery.[13,14]

Patient prerequisite for induction

- Assessment of maternal parameters
  - Confirm the indication for induction
  - Review for contraindication to labour and/or vaginal delivery
  - Assess the shape and adequacy of bony pelvis
  - Assess the cervical status by Bishop score
  - Review risk and benefit of induction of labour with patient and the family
- Assessment of fetal parameters
  - Confirm the gestational age
  - Estimate fetal weight
  - Determine fetal position
  - Determine fetal well being

Indication[15]

- Obstetric indication:
  - Post term pregnancy
  - Preeclampsia, eclampsia
  - Previous unexplained IUD
  - Fetal compromise (eg, severe fetal growth restriction, isoimmunization)
  - Premature rupture of membranes
  - Malformed fetus
  - Severe hydraminos
  - Unexplained oligo hydraminos
  - Gestational diabetes mellitus
  - Abruptio placentae
  - Chorioamnionitis
  - Fetal demise
- Maternal medical conditions
  - diabetes mellitus
  - chronic renal disease,
  - chronic pulmonary disease
  - chronic hypertension

Contraindication[16]

- Absolute
  - Active genital herpes infection
  - Serious chronic medical condition
  - Pelvic Structural abnormality
  - Cephalopelvic disproportion major degree
  - Abnormal fetal lie [transverse lie, oblique lie]
  - Umbilical cord prolapse
  - Placenta previa of major degree and vasa previa
  - Previous classical Cesarean section or other transfundal uterine surgery
  - Contraindication specific to the inducing drug used.
- Relative
  - Invasive cervical cancer
  - Uterine overdistension [multiple pregnancy, poly hydraminos]
  - Malpresentation [breech]
  - Fetal macrosomia
  - Low lying placenta
  - Unexplained vaginal bleeding
  - Cord presentation

- Myomectomy involving uterine cavity
- Abnormal fetal heart pattern

Bishop Scoring System[17]					
	Factor				
Score	**Dilation (cm)**	**Effacement (%)**	**Station***	**Cervical Consistency**	**Position of Cervix**
0	Closed	0-30	-3	Firm	Posterior
1	1-2	40-50	-2	Medium	Midposition
2	3-4	60-70	-1,0	Soft	Anterior
3	5-6	80	+1,+2	--	--
*Station reflects - 3 to +3 scale.					

Methods of Labor Induction[18]

I-Non pharmacologic methods

- **Natural method**
  - Relaxation techniques
  - Sexual intercourse
  - Nipple stimulation
  - Hot Bath / Castor oil / Enemas
  - Foods
  - Cumin Tea
  - Several herbs
  - Acupressure

- **Mechanical methods**
  - Osmotic dilators
    - Laminaria
    - dilapan
  - Balloon devices
    - Foleys
    - Bougie

II- **Surgical methods**

- stripping the membranes
- Amniotomy

III- **Pharmacological methods**

- Oxytocin
- Prostaglandin
  - Misoprostol [E1]
  - Dinoprostone [E2]
- Mifepristone

The addition of oxytocin along with the use of the Foley catheter does not appear to shorten the time of delivery in a randomized controlled trial[19]. Studies examining extraamniotic saline infused through the Foley catheter compared with use of the Foley catheter with concurrent oxytocin administration report conflicting results on the time from induction to delivery[20]. Differences in methodology could explain the opposing findings. The Foley catheter was a reasonable and effective

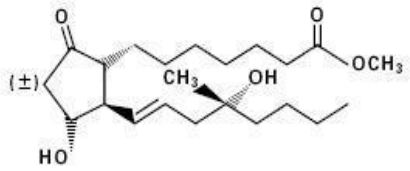
alternative for cervical ripening and inducing labor. Intracervical or intravaginal PGE2 commonly was used and was superior to placebo or no therapy in promoting cervical ripening[21]. Several prospective randomized clinical trials and two meta-analyses have demonstrated that PGE1 (misoprostol) was an effective method for cervical ripening[22]. Misoprostol administered intravaginally had been reported to be either superior to or as efficacious as dinoprostone gel[23]. Vaginal misoprostol had been associated with less use of epidural analgesia, more vaginal deliveries within 24 hours, and more uterine tachysystole with or without FHR changes compared with dinoprostone and oxytocin. It was difficult, however, to compare the results of studies on misoprostol because of differences in endpoints, including Bishop Score, duration of labor, total oxytocin use, successful induction, and cesarean delivery rate[24]. Pharmacologic methods for cervical ripening did not decrease the likelihood of cesarean delivery.

In December 2000, the American College of Obstetricians and Gynecologists reaffirmed its recommendation for use of the drug because of proven safety and efficacy[25]. Misoprostol tablets placed into the vagina

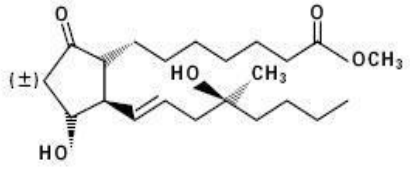
were either superior to or equivalent in efficacy when compared with intracervical prostaglandin E_2 gel[26]. Misoprostol use may decrease the need for oxytocin, achieve higher rates of vaginal delivery within 24 hours of induction, and reduce induction-to-delivery intervals. Misoprostol costs less than compared with dinoprostone gel and it does not need refrigeration.

Misoprostol - Clinical Pharmacology

Misoprostol is a synthetic prostaglandin E1 analog. Misoprostol contains approximately equal amounts of the two diastereomers presented below with their enantiomers indicated by (±):



and



$C_{22}H_{38}O_5$ M.W. = 382.5

(±) methyl 11α,16-dihydroxy-16-methyl-9-oxoprost-13E-en-1-oate

Pharmacokinetics[27]

Misoprostol is a water soluble compound.[28] Misoprostol is extensively absorbed, and undergoes rapid de-esterification to its free

acid (Misoprostolic acid), which is responsible for its clinical activity and, unlike the parent compound, is detectable in plasma. The alpha side chain undergoes beta oxidation and the beta side chain undergoes omega oxidation followed by reduction of the ketone to give prostaglandin F analogs. In normal volunteers, Misoprostol is rapidly absorbed after oral administration with a Tmax of Misoprostol acid of 12 ± 3 minutes and a terminal half-life of 20–40 minutes.

Route[5]	**Onset of action**[5]	**Duration of action**[5]
Oral *	8 min	~ 2 h
Sublingual	11 min	~ 3 h
Vaginal	20 min	~ 4 h
Rectal	100 min	~ 4 h

Pharmacodynamics[27]

Misoprostol has both antisecretory (inhibiting gastric acid secretion) and (in animals) mucosal protective properties. NSAIDs inhibit prostaglandin synthesis, and a deficiency of prostaglandins within the gastric mucosa may lead to diminishing bicarbonate and mucus secretion and may contribute to the mucosal damage caused by these agents. Misoprostol can increase bicarbonate and mucus production, but in man this has been shown at doses 200 mcg and above that are also antisecretory.

Uterine Effects

Misoprostol has been shown to produce uterine contractions that may endanger pregnancy

Indications and Usage for Misoprostol

1. Misoprostol is indicated for the prevention of gastric ulcer associated with the use of nonsteroidal anti-inflammatory drugs (NSAIDs), including aspirin, in patients at high risk of complications from gastric ulcer, such as the elderly, and in patients with concomitant disease or patients at high risk of developing gastric ulceration, such as those with a history of ulcer.[29]

2. The efficacy and tolerability of mifepristone in combo with misoprostol for termination of early pregnancy (up to 49 days of amenorrhea) are established.[30]

3. Misoprostol, in very low doses, was a remarkably efficient and safe method for induction of labor.[31]

Pregnancy: Category X[32]

Teratogenic effects

Several reports in the literature associate the use of Misoprostol during the first trimester of pregnancy with skull defects, cranial nerve palsies, facial malformations, and limb defects.[33]

Nonteratogenic effects

Misoprostol may endanger pregnancy (may cause abortion) and thereby cause harm to the fetus when administered to a pregnant woman.[34]

Labor and delivery

Misoprostol can induce or augment uterine contractions. Vaginal administration of Misoprostol, outside of its approved indication, has been used as a cervical ripening agent, for the induction of labor and for treatment of serious postpartum hemorrhage in the presence of uterine atony[35]. A major adverse effect of the obstetrical use of Misoprostol is hyperstimulation of the uterus which may progress to uterine tetany with marked impairment of uteroplacental blood flow, uterine rupture (requiring surgical repair, hysterectomy, and/or salpingo-oophorectomy), or amniotic fluid embolism. Pelvic pain, retained placenta, severe genital bleeding, shock, fetal bradycardia, and fetal and maternal death have been reported.[27]

There may be an increased risk of uterine tachysystole, uterine rupture, meconium passage, meconium staining of amniotic fluid, and cesarean delivery[36] due to uterine hyperstimulation with the use of higher doses of misoprostol. The risk of uterine rupture increases with

advancing gestational ages and with prior uterine surgery, including cesarean delivery.[37] Grand multiparity also appears to be a risk factor for uterine rupture.

The effect of Misoprostol on the later growth, development, and functional maturation of the child when Misoprostol is used for cervical ripening or induction of labor had not been established yet. Information on misoprostol's effect on the need for forceps delivery or other intervention is unknown.

Nursing mothers

Caution should be exercised when Misoprostol is administered to a nursing woman.[27]

Pediatric Use

Safety and effectiveness of Misoprostol in pediatric patients have not been established.[27]

Adverse Reactions

1. Diarrhea
2. Abdominal pain.
3. Nausea
4. Flatulence
5. Headache

6. Dyspepsia
7. Vomiting
8. Constipation
9. Spotting
10. Cramps
11. Hypermenorrhea
12. Menstrual disorder
13. Dysmenorrhea

Misoprostol Dosage and Administration[38]

Indication	Dosage
Nsaid's ulcer prophylaxis	200 mcgx4 times
Induced abortion (0-12 weeks)	800mcg vaginally 12-hrly x3
Missed abortion (0-12 weeks)	800mcg vaginal 3-hrly *or* sublingual 600mcg 3-hourly
Incomplete abortion (0-12weeks)	600mcg orally single dose
Induced abortion (13-22 weeks)	400mcg vaginally 3-hrly x5
Intrauterine fetal death	13-17 wks: 200mcg pv 6-hrly. 18-26 wks: 100mcg pv 6-hrly. 27+ wks: 25-50mcg pv 4-hrly
Induction of labour	25mcg vaginally 4-hrly *or* 50 mcg orally 4-hrly *or* 20mcg oral solution 2-hrly
PPH prophylaxis	600mcg orally or sublingually stat
PPH treatment	600mcg orally or sublingually stat
Cervical ripening	400mcg vaginally 3h before procedure

Overdosage

The toxic dose of Misoprostol in humans has not been determined. Cumulative total daily doses of 1600 mcg have been tolerated, with only symptoms of gastrointestinal discomfort being reported[38].

Contraindications

Misoprostol should not be taken by pregnant women to reduce the risk of ulcers induced by non-steroidal anti-inflammatory drugs (NSAIDs). Misoprostol should not be taken by anyone with a history of allergy to prostaglandins.

Precautions

Caution should be employed when administering Misoprostol to patients with pre-existing cardiovascular disease.

A. Aronsson et al[40] had studied the effect of misoprostol administered by different routes on pregnant uterine contractility. They had observed an increase in uterine tonus, which occurred after a significantly shorter time following oral (7.8 min) and sublingual (10.7±11.5 min) than after vaginal (19.4 min) treatment. The time to maximum tonus elevation was also significantly shorter (39.5, 47.1±51.7 and 62.2 min for the three groups respectively). Regular uterine contractions developed in all subjects following sublingual and vaginal

administration but not after oral administration. The increase in uterine activity measured in Montevideo Units was significantly higher after 2 h and thereafter for sublingual and vaginal treatment than for oral misoprostol. Based on recording of uterine activity, sublingual misoprostol acts as rapidly as oral treatment, while development of contractions was similar to that seen following vaginal administration.

AH Nassar et al.[8] had studied the patient satisfaction with two routes of misoprostol for term labour induction. Despite a similar proportion reporting the labour induction as more painful than expected in both groups, a significantly lower proportion mentioned that the pelvic examinations were very painful in the sublingual group (19.7 versus 36.1%, relative risk [RR] 0.5, 95% CI 0.3–0.9). Request for analgesia was similar in both groups. More women in the sublingual group thought that the labour experience was better than expected (RR 2.0, 95% CI 1.2–3.3), had a positive attitude towards induction in subsequent pregnancies (RR 1.6, 95% CI 1.1–2.3) and preferred the same route in subsequent pregnancies (RR 3.1, 95% CI 2.2–4.5). Mean number of misoprostol doses, oxytocin augmentation, tachysystole and hyperstimulation, induction to vaginal delivery interval, vaginal delivery after a single dose, vaginal birth within 12 and 24 hours, and caesarean delivery rates were similar in both groups. They had concluded that

sublingual misoprostol (50 micrograms) is associated with a significantly higher patient satisfaction rate compared with a similar dose of vaginal misoprostol. Sublingual administration offers additional choice to women, in particular those wishing to avoid vaginal administration.

A Bartusevicius et al.[4] studied the efficacy and safety of 50 μg of sublingual misoprostol with 25 μg of vaginal misoprostol administered for labour induction at term. They found that the induction to vaginal delivery time was significantly shorter in the sublingual group (15.0 ± 3.7 hours) compared with the vaginal group (16.7 ± 4.1 hours, $P = 0.03$). The incidence of tachysystole was more than three-fold higher in the sublingual than in the vaginal group (14 versus 4.3%; RR 3.3, 95% CI 0.9–11.6), but this was not statistically significant. There were no significant differences in the incidence of hypertonus or hyperstimulation syndrome, mode of delivery, interventions for fetal distress or neonatal outcomes between the two groups

Yvette Pernella Geels et al.[41] had studied the complications and effectiveness of induction after vaginal and sublingual administration of misoprostol for labor induction in women with intra-uterine fetal death (IUFD). In the vaginal group 28.6% had one or more complications compared to 21.7% in the sublingual group. In the sublingual group three inductions did not lead to delivery within 48 hours (13%), compared to

four in the other group (19%).The mean induction to delivery time in the sublingual group was13 hours and17 hours in the vaginal group. They had concluded that both sublingual and vaginal misoprostol were safe and efficient for labor induction in women with IUFD.


Material &
Methods

MATERIALS AND METHODS

This study was conducted in ANNAL GANDHI MEMORIAL GOVERNMENT HOSPITAL, TIRUCHIRAPALLI, TAMILNADU in the Department of obstetrics and gynecology during the period of June 2009 – August 2010 after getting approval from ethical committee. 120 patients those for labour induction at term were included in this study. 60 patients were administered sublingual misoprostol and remaining 60 patients were administered vaginal misoprostol.

Inclusion criteria

- Live singleton pregnancy at a gestational age of 37 completed weeks or more with a medical or obstetric indication for induction including gestational age ≥ 41 weeks [PD], prelabour rupture of membrane [PROM], mild preeclampsia [MPE] and gestational diabetes mellitus [GDM]
- Both nulliparous and multiparous women
- A cephalic presentation
- An unfavorable cervix (Bishop's score less than or equal to 6)
- A reassuring fetal heart tracing.

Exclusion Criteria

- Multiple gestation
- Malpresentation (presentation other than cephalic)
- Previous uterine surgery including cesarean surgery
- Known contraindications to the use of prostaglandins (e.g. asthma)
- Grandmultiparity (more than 5)
- Need for immediate delivery
- Chorioamnionitis or hyperthermia > 38ºC
- Active vaginal bleeding
- Ultrasonically estimated oligohydramnios, polyhydramnios, suspicion of fetal malformation, macrosomia or growth restriction.

Women who fulfilled these criteria were included in this study. Randomization was done by computer prepared data. They had been divided into 2 groups.

Group A: sublingual misoprostol [SLM]

60 patients for labour induction were randomly allocated for 25 microgram sublingual misoprostol administration every 4^{th} hourly for maximum of 6 doses.

Group B: vaginal misoprostol [VM]

60 patients for labour induction were randomly allocated for 25 microgram vaginal misoprostol administration every 4th hourly for maximum of 6 doses.

Method

Each women was allocated to receive 25 microgram sublingual misoprostol every 4th hourly for maximum of 6 doses in group A and 25 microgram vaginal misoprostol administration every 4th hourly for maximum of 6 doses. If patient had atleast three regular contraction in 10 minutes, enteres active phase of labour [regular uterine contraction and cervical dilatation greater than or equal to 3 cms] and cervix favourable for amniotomy [Bishop score greater than or equal to 8], then subsequent dose of misoprostol was withheld. As soon as fetal head engagement and cervical dilation permitted, amniotomy was performed, followed by oxytocin augmentation if the frequency of contractions was less than three per 10 minutes each lasting for 45 seconds or the contractions pattern was dysfunctional. Oxytocin was administered not earlier than 4 hours after the last misoprostol dose, starting at 1 mU/minute and increased by 1 mU/minute every 15 minute until adequate contractions persisted. Continuous fetal cardiotocography was used throughout the study.

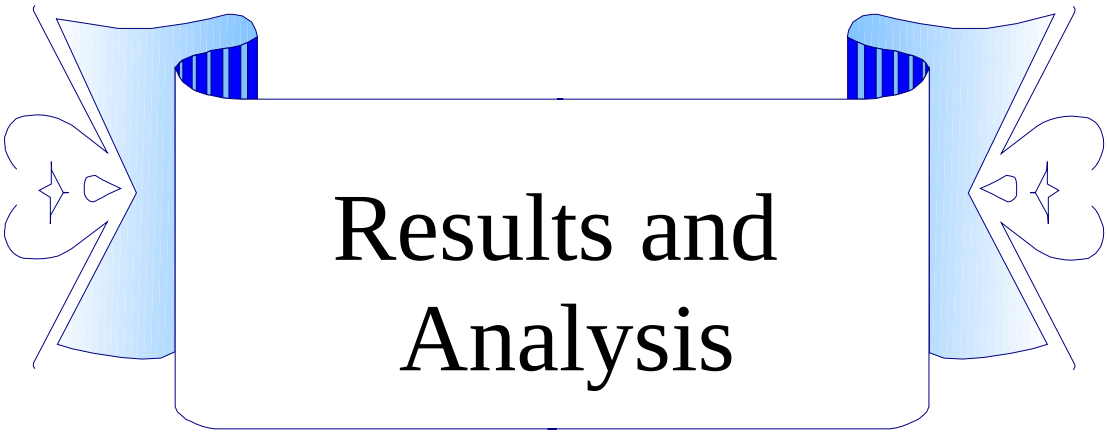
Tachysystole was defined as at least six contractions per 10 minutes during two consecutive 10-minute periods. Hypertonus was defined as a single uterine contraction lasting for 2 minutes or more. Hyperstimulation syndrome was defined as the presence of tachysystole or hypertonus associated with a nonreassuring FHR pattern (fetal tachycardia, late decelerations, severe variable decelerations or loss of FHR variability). All the episodes of hyperstimulation syndrome were included in the analysis regardless of the interval from the time of misoprostol administration to the occurrence of the abnormal FHR pattern. Recognised episodes of hyperstimulation were managed by stopping the oxytocin infusion, maternal repositioning, hydration and oxygen administration. In the sublingual group, the woman was advised to spit out the medication and wash her mouth, and for those in the vaginal group, the tablet was removed when possible. Labour induction was considered a failure if a woman did not enter the active phase of labour following six doses of misoprostol. The woman was then offered a caesarean section.

Following outcome variables were measured.

1. Number of women delivered vaginally within 24 hours of the first dose of misoprostol

2. Interval from the start of induction to vaginal delivery / induction delivery interval.
3. Cesarean rates
4. Number of misoprostol doses given
5. Need for oxytocin augmentation
6. Number of per vaginal examination
7. Uterine tachysystole rates
8. Uterine hypertonus rates
9. Uterine hyperstimulation rates
10. Other Maternal adverse effects
11. Birth weight of baby
12. Incidence of meconium-stained amniotic fluid
13. Neonatal intensive care unit (NICU) admissions.
14. 5 min APGAR score less than 7.

The means between the groups were compared using an unpaired, two-tailed Student's *t* test. Categorical variables were analysed using chi-square test. $P < 0.05$ was considered statistically significant. For discrete data, relative risk (RR) with 95% confidence intervals (CI) was used.

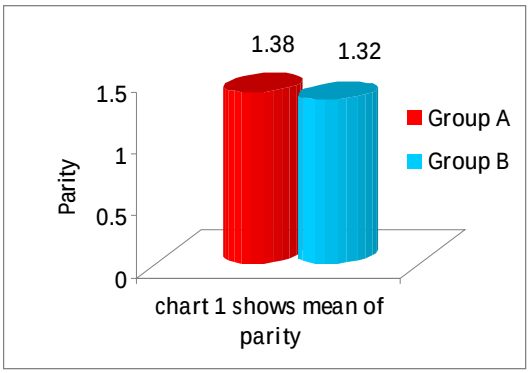

Results and
Analysis

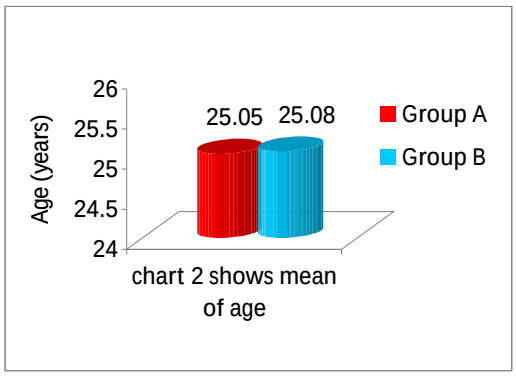
RESULTS AND ANALYSIS

Table 1: Comparison of age [years] and parity

	Group A[SLM]	Group B [VM]
Age [years]	25.07 ± 3.97	25.08 ± 3.70
Parity	1.38 ± 0.72	1.32 ± 0.57
Primigravida	42[70]	43[71]
Multigravida	18[30]	17[29]

Table 1 shows mean and standard deviation of age and parity in both groups. Primigravida and multigravida were shown in number [percentage]. There was no significant difference among the groups.





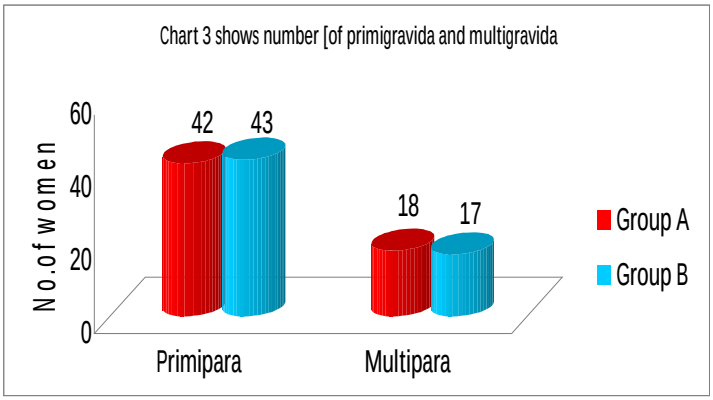


Table 2: Comparison of gestational age [weeks]

	Group A[SLM]	Group B [VM]	P value
Gestational age [weeks]	39.92±1.92	39.32±1.59	0.849

Table 2 shows mean and standard deviation of gestational age [weeks] in both groups. There was no significant difference among the groups.

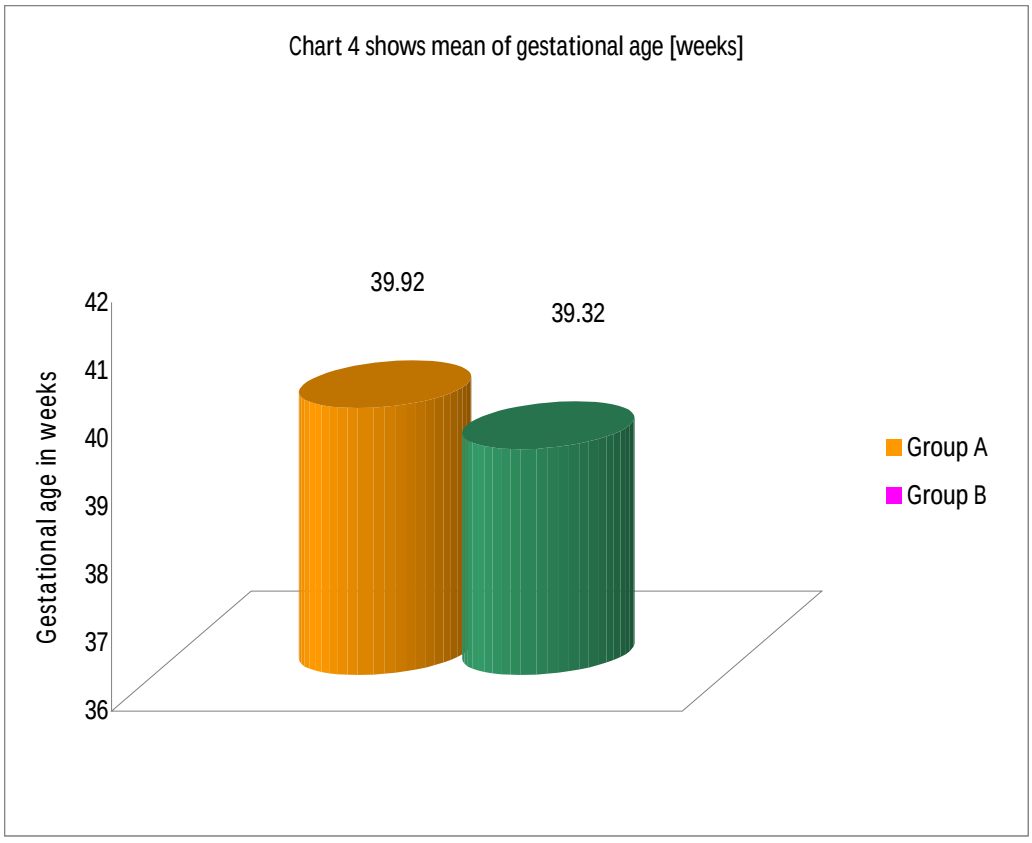


Table 3: Comparison of bishop score

	Group A[SLM]	Group B [VM]	P value
Bishop score	4.03±0.81	4.05±0.59	1.00

Table 3 shows mean and standard deviation of Bishop score in both groups. There was no significant difference among the groups.

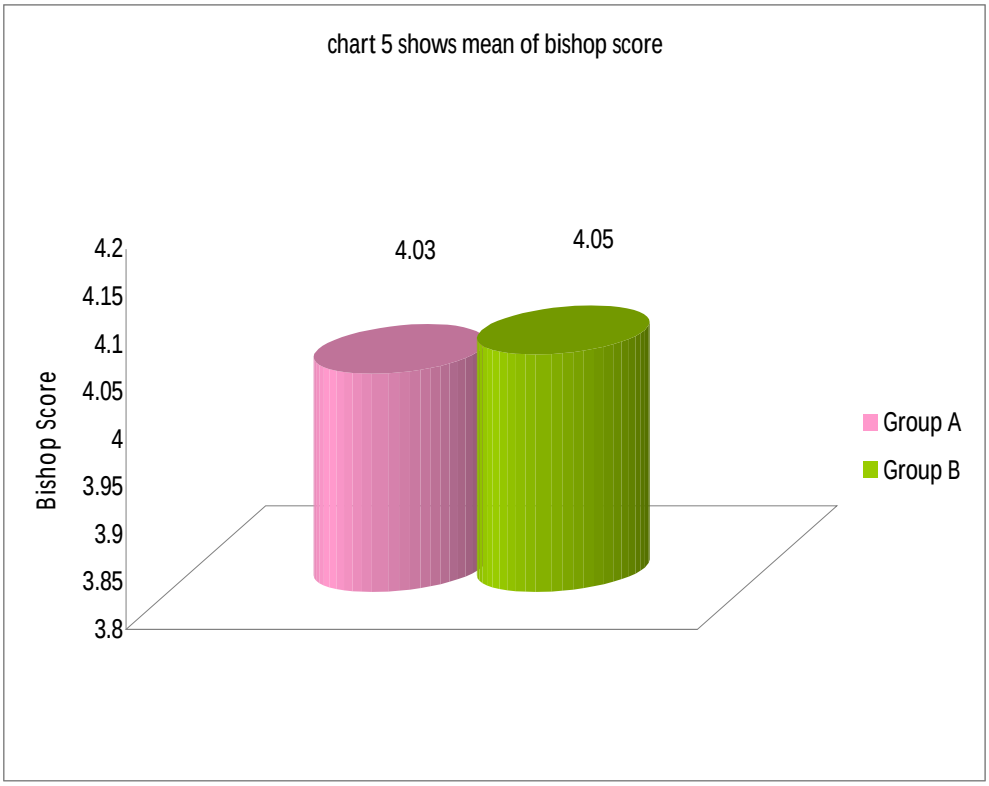


Table 4: Comparison of indication for induction

	Group A[SLM]	Group B [VM]
Post term [>41 weeks]	28[46.7]	25[41.7]
Mild preeclampsia	11[18.3]	14[23.3]
Gestational diabetes mellitus	4[6.7]	3[5]
Prelabour rupture of membrame	17[28.3]	18[30]

Table 4 shows number [percentage] of indication for induction in both groups. There was no significant difference among the groups.

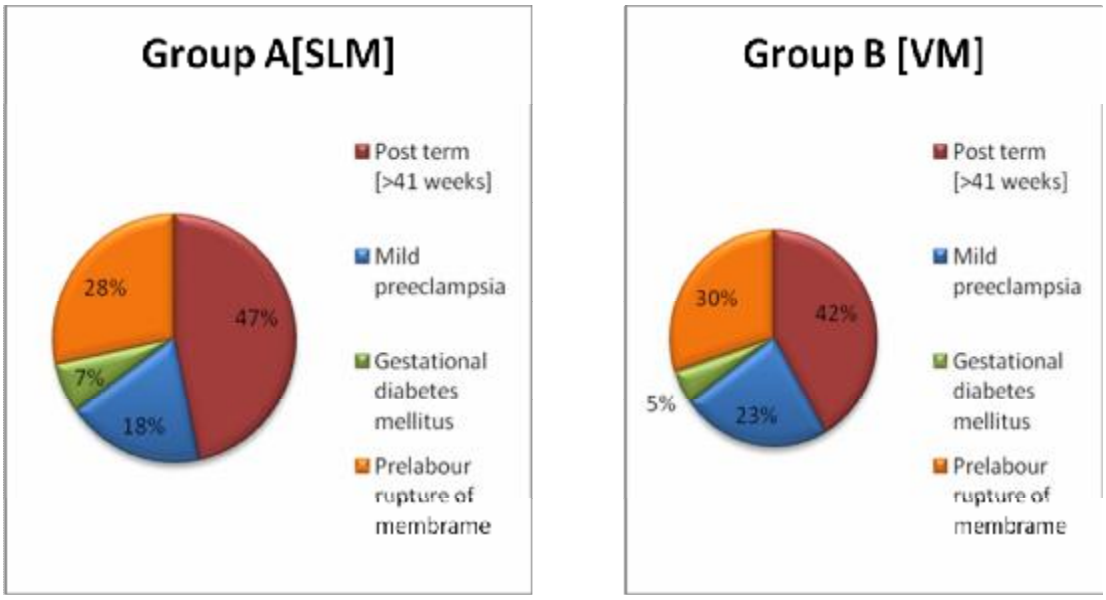


Chart 6 shows percentage of indication of induction.

Table 5: Comparison of total doses of misoprostol

	Group A[SLM]	Group B [VM]	P value
Total doses of misoprostol	1.85±1.02	2.3±1.2	<0.05

Table 5 shows mean and standard deviation of total doses of misoprostol in both groups. Misoprostol used was significantly lower in sublingual route than vaginal route [p<0.05].

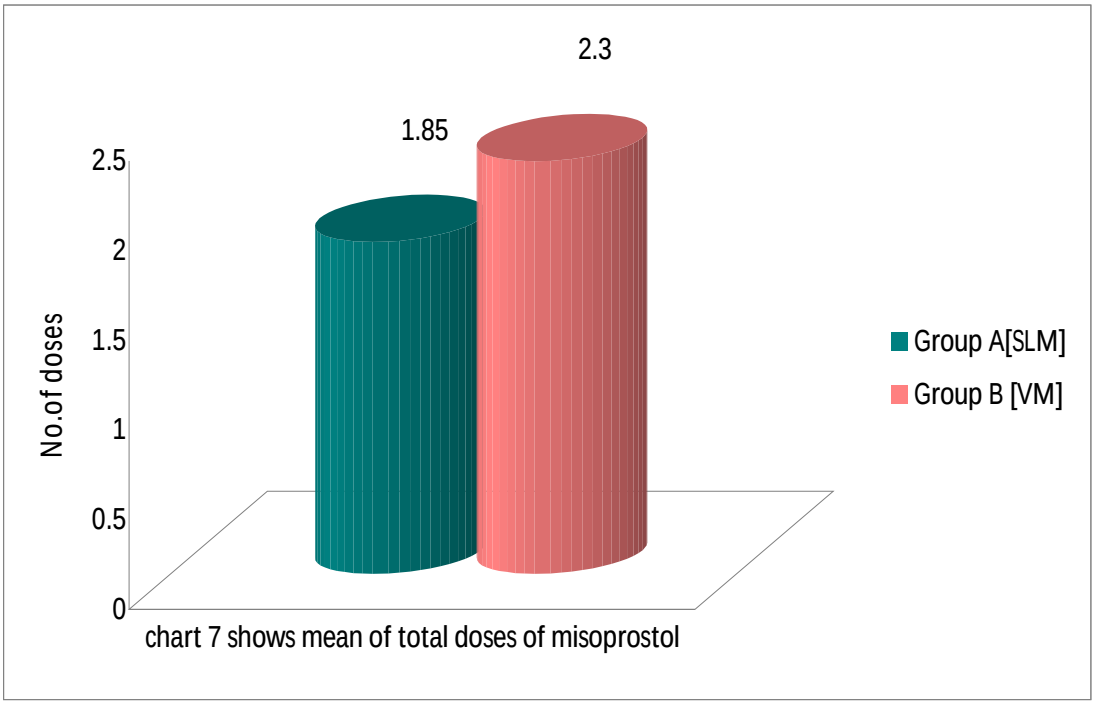


chart 7 shows mean of total doses of misoprostol

Table 6: Comparison of number of vaginal delivery in < 24 hours of induction

	Group A[SLM]	Group B [VM]	RR [CI 95%]
Vaginal delivery < 24 hours	52[86.7]	50[83.3]	1.04 [0.89 -1.20]

Table 6 shows number [percentage] of vaginal delivery in <24 hours in both groups. There was no significant difference among the groups.

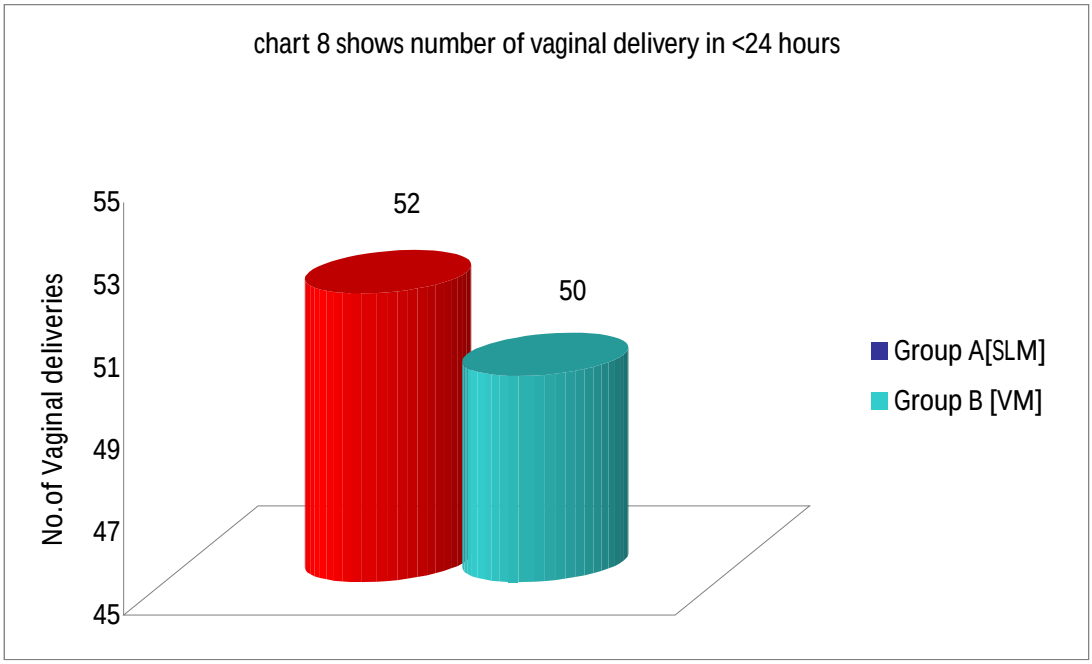


Table 7: **Comparison of number of pelvic examination**

	Group A[SLM]	**Group B [VM]**	**P value**
Number of pelvic examination	5.75±2.05	8.22±2.04	P<0.05

Table 7 shows mean and standard deviation of number of pelvic examination in both groups. Pelvic examination was significantly lower in sublingual route misoprostol than vaginal route of administration [p<0.05].

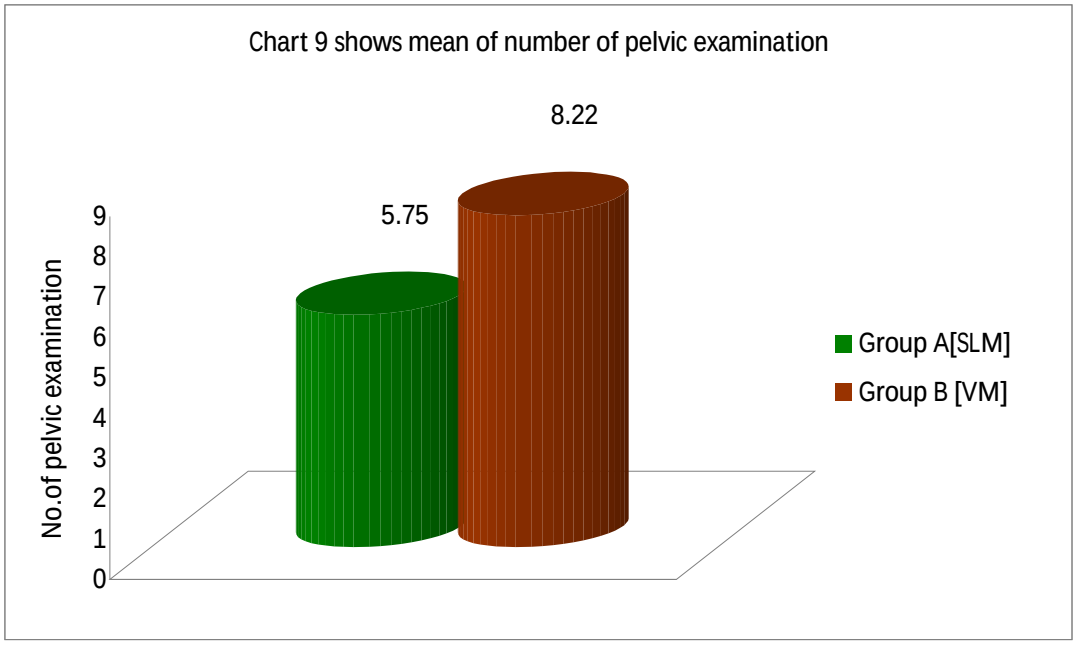


Table 8: Comparison of oxytocin use

	Group A[SLM]	Group B [VM]	RR [CI 95%]
Oxytocin use	45[75]	47[78.3]	0.95 [0.79 – 1.17]

Table 8 shows number [percentage] of patients where oxytocin was used in both groups. There was no significant difference among the groups.

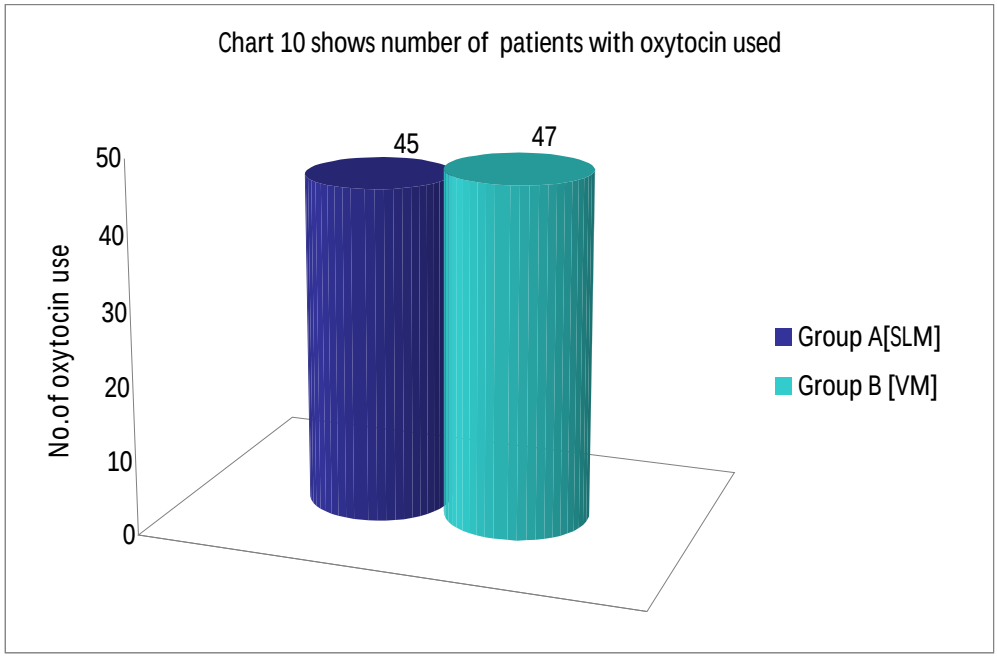


Table 9: Comparison of induction delivery interval [minutes]

	Group A[SLM]	Group B [VM]	P value
Induction delivery interval (min)	650.98±250.83	779.7±269.97	P<0.05
Induction vaginal delivery interval (min)	597.42±186.47	720±195.47	P<0.005

Table 9 shows mean and standard deviation of induction delivery interval including caesarean section [minutes] and induction vaginal delivery interval [minutes] in both groups. Induction delivery interval including caesarean section and induction vaginal delivery interval was significantly lower in sublingual route misoprostol than vaginal route of administration [p<0.05].

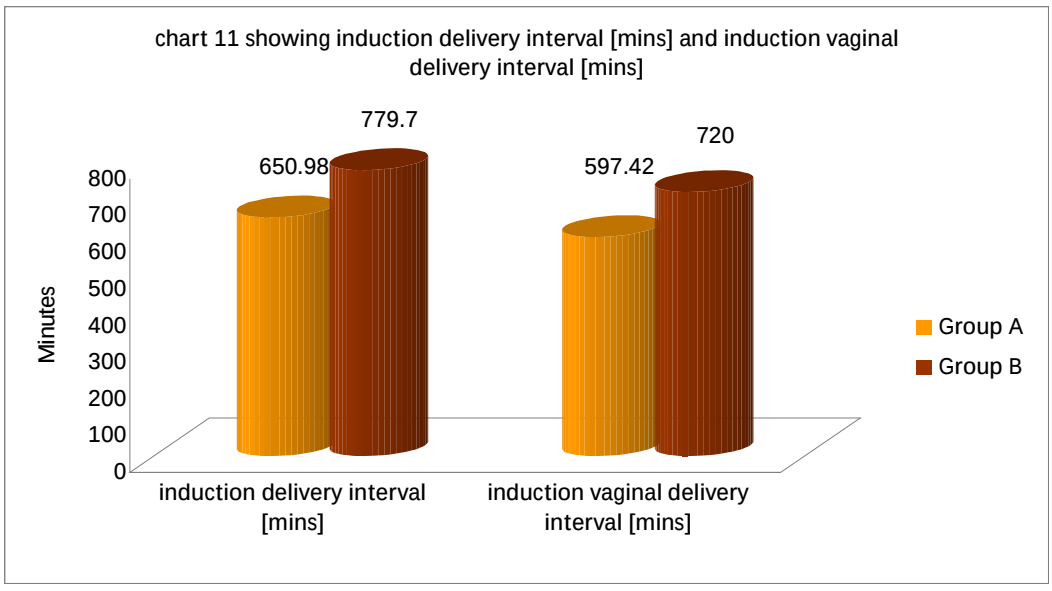


Table 10: Comparison of mode of delivery

	Group A[SLM]	Group B [VM]	RR [CI 95%]
Spontaneous vaginal delivery	49[81.7]	45[75]	1.09 [0.90 – 1.32]
Instrumental vaginal delivery	3[5]	5[8.3]	0.6 [0.15 – 2.40]
Caesarean section	8[13.3]	10[16.7]	0.8 [0.34 -1.89]

Table 10 shows number [percentage] of mode of delivery in both groups. There was no significant difference among the groups.

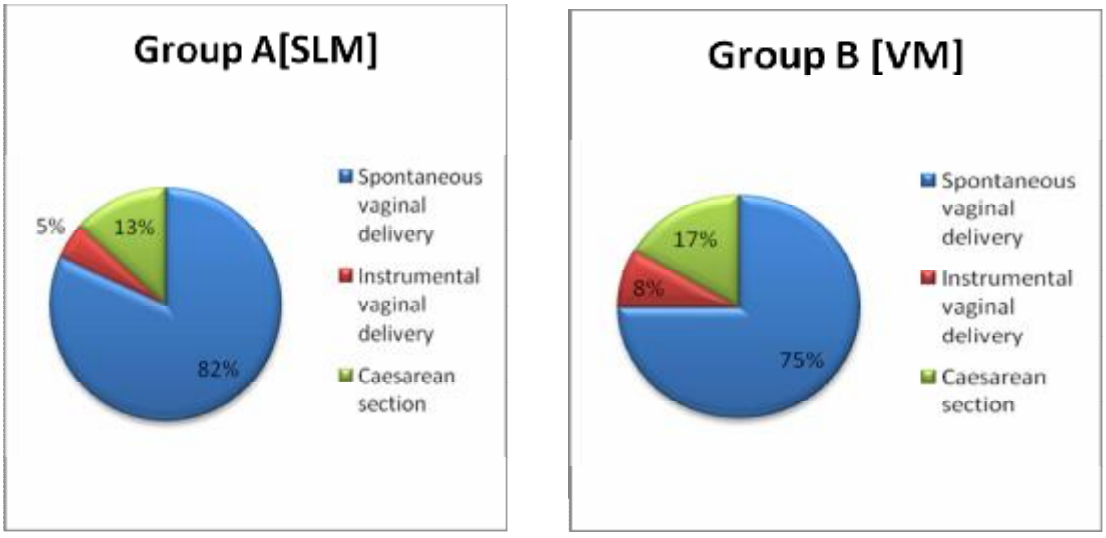


Chart 12 shows percentage of mode of delivery

Table 11: Comparison of indication for caesarean section

	Group A[SLM]	Group B [VM]	RR [CI 95%]
Fetal distress	2[25]	3[30]	0.83 [0.18 – 3.84]
Non progress of labour / arrest of labour	4[50]	4[40]	1.25[0.45 – 3.49]
Failed induction	2[25]	3[30]	0.83 [0.18 – 3.84]

Table 11 shows number [percentage] of indication for caesarean section in both groups. There was no significant difference in fetal distress, non progress of labour / arrest of labour and failed induction among the groups.

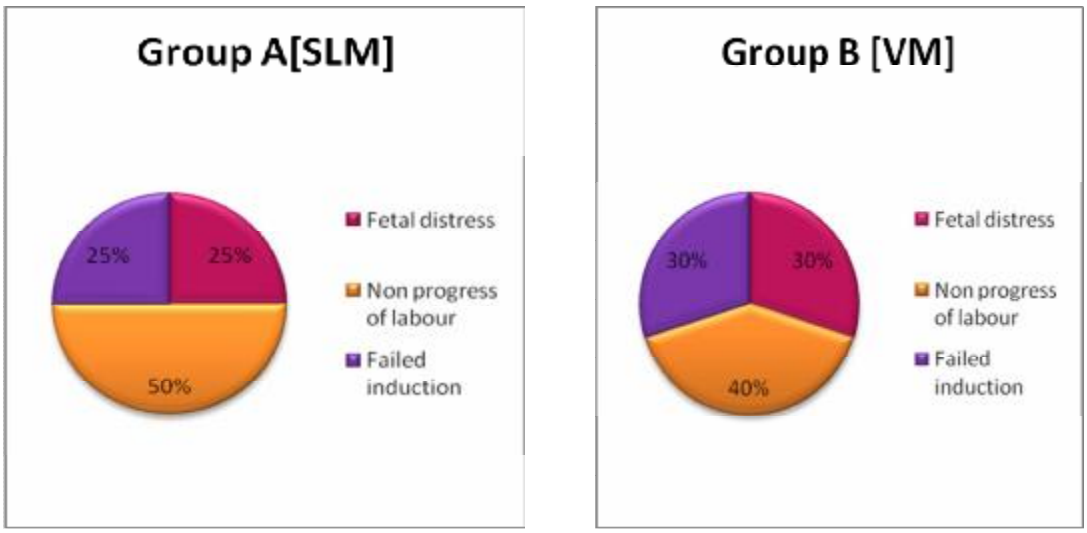


Chart 13 shows percentage of indication for caesarean section

Table 12: Comparison of maternal uterine complications

	Group A[SLM]	Group B [VM]	RR [CI 95%]
Tachysystole	6[10]	6[10]	1 [0.34 -2.93]
Hypertonus	1[1.7]	1[1.7]	1 [0.06 – 15.62]
Hyperstimulation syndrome	3[5]]	2[3.3]	1.5 [0.26 – 8.66]

Table 12 shows number [percentage] of maternal uterine complication in both groups. There was no significant difference among the groups. Hyperstimulation syndrome had been treated by maternal left lateral position, O2 administration and infusing intravenous fluids. All the patients responded and all patients had delivered vaginally except one delivered by outlet forceps for failed maternal effort in vaginal group.

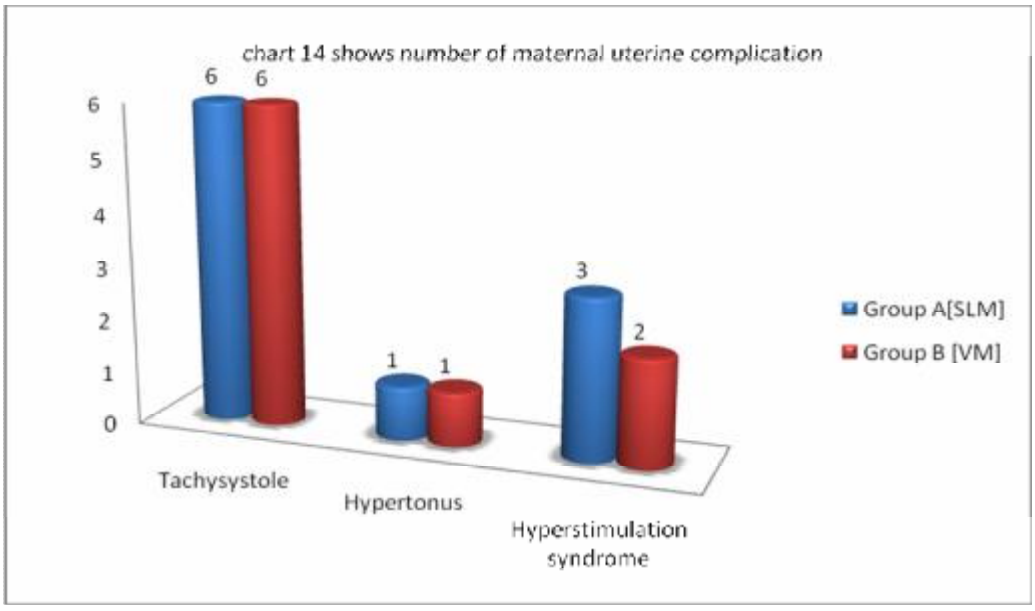


Table 13: Comparison of other maternal complications

	Group A[SLM]	Group B [VM]	RR [CI 95%]
Vomiting	2[3.3]	2[3.3]	1 [0.15 – 6.87]

Table 13 shows number [percentage] of other maternal complications in both groups. There was no significant difference among the groups.

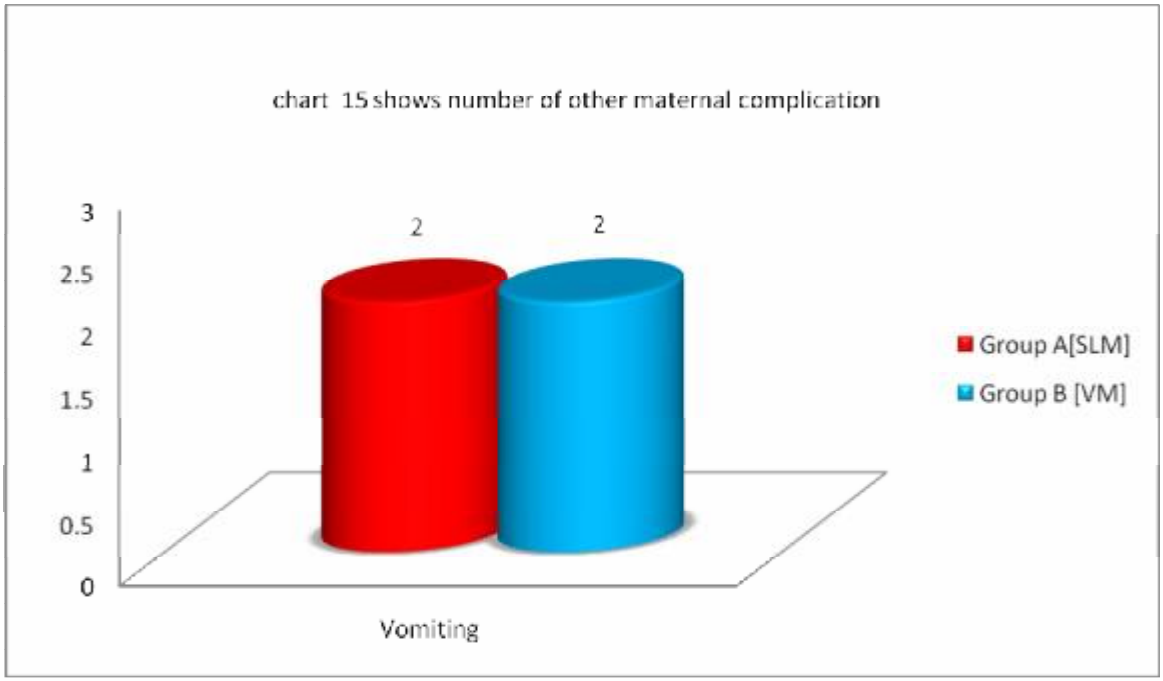


Table 14: Comparison of birth weight of baby [kilograms]

	Group A[SLM]	Group B [VM]	P value
Baby birth weight [kgs]	2.89±0.23	2.90±0.19	0.83

Table 14 shows mean and standard deviation of baby birth weight [kilograms] in both groups. There was no significant difference among the groups.

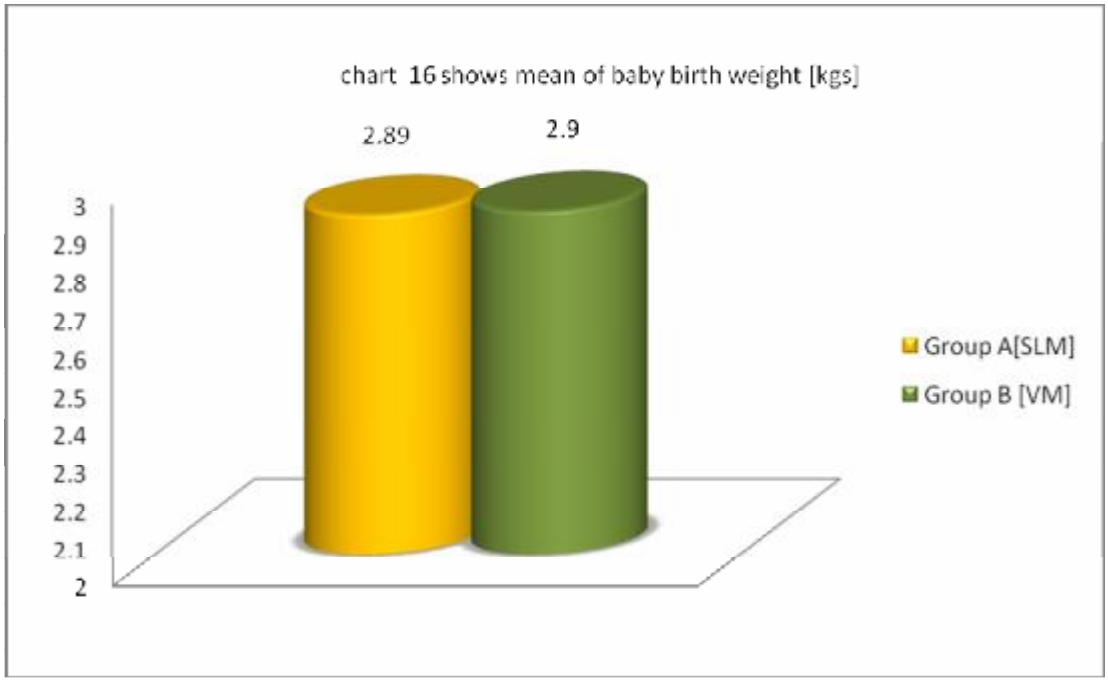
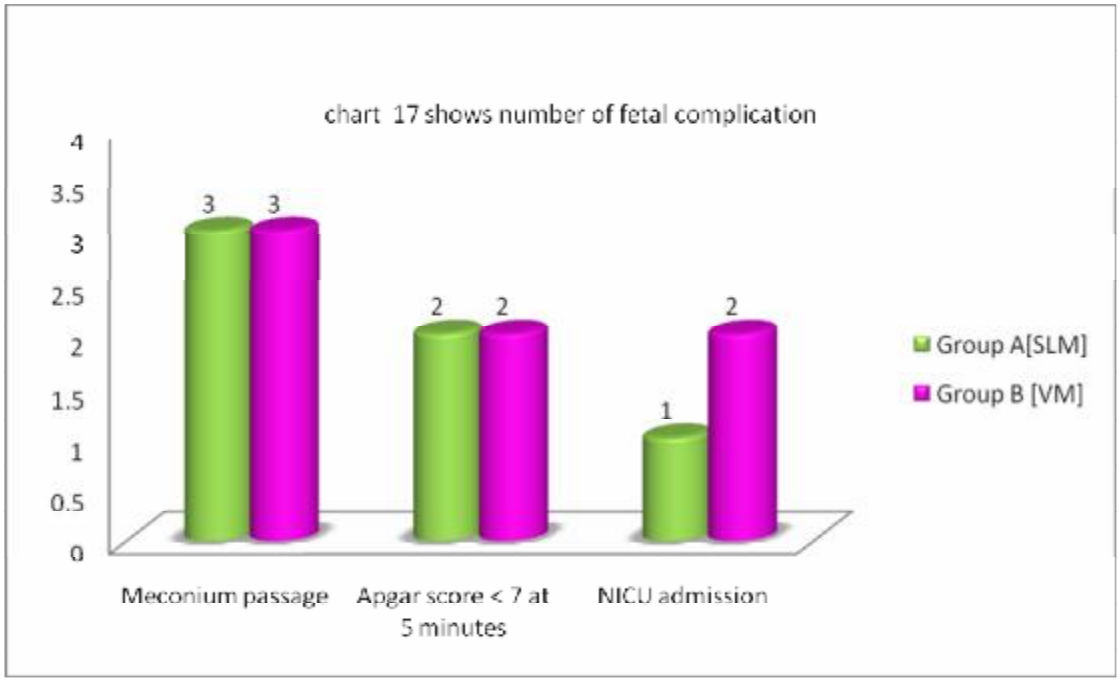
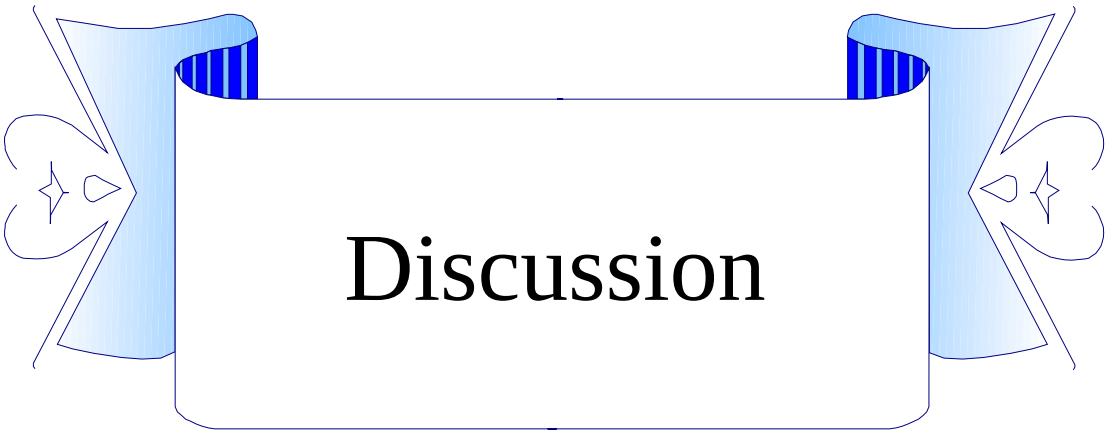


Table 15: Comparison of fetal complications

	Group A[SLM]	Group B [VM]	RR [CI 95%]
Meconium passage	3[5]	3[5]	1 [0.21 – 4.76]
Apgar score < 7 at 5 minutes	2[3.3]	2[3.3]	1 [0.15 – 6.87]
NICU admission	1[1.6]	2[3.3]	0.5 [0.05 – 5.37]

Table 15 shows number [percentage] of fetal complication in both groups. There was no significant difference among the groups.




Discussion

DISCUSSION

In our study we had selected 180 patients as eligible candidates and 120 patients were included in our study. So far as per pub med search machine sublingual misoprostol study was done on 160, 120, 140, 150 and 170 patients.

There was no difference in age, parity, gestational age, bishop score and indication of induction among the both groups in our study. The results had showed that 25μg of sublingual misoprostol administration resulted in significantly shorter induction to delivery interval [$p < 0.005$], with a lower number of misoprostol doses required [$p < 0.01$] and lesser number of pelvic examination [$p < 0.05$] required as compared with those administered 25 μg of vaginal misoprostol.

In Tang et al.[5] study, the sublingual route has been shown to produce significantly higher serum peak concentration of misoprostol than either oral or vaginal administration. In addition, the area under the curve for plasma levels over 4 and 6 hours was significantly greater following sublingual administration than for either oral or vaginal administration. A recently published study evaluated the effects of misoprostol on uterine contractility following different routes of administration[42]. The sublingual application of misoprostol has, with

regard to effects on the myometrium, had rapid effect on uterine contractility as oral administration and the bioavailability was similar to that following vaginal administration. We had administered sublingual dosage every 4th hourly. These findings may explain the significant induction delivery interval with sublingual misoprostol in our study.

A Bartusevicius et al[4] had also observed same result in their study. They had used 50 μg of sublingual misoprostol in contrast to 25 μg in our study. Our study had showed that 25 μg administered sublingual was equivalent to 25 μg administered vaginally in their effect like shortening the induction delivery time and also the number of misoprostol tablets used for induction.it may decrease the cost of management. Feitossa et al.[43] had observed Vaginal delivery rates were 57% in the sublingual group and 69% in the vaginal group (RR, 0.8; 95% CI, 0.6–1.1). There were 11 cases of fetal distress in the sublingual group and 4 cases in the vaginal group (RR, 2.7; 95% CI, 0.9–8.2). They had used 25 μg of sublingual misoprostol every 6 hourly. Though they had observed significant difference in value between the groups, percentage of vaginal delivery was very small compared to our study [57% & 69% Vs 81.7% & 75%]. It may be due to their higher dosing interval [6 hours Vs 4 hours] than our study.

Tang et al.[5] on studying pharmacokinetics of misoprostol in different route of administration had found that at the end of 6 h, the serum levels of MPA in the vaginal groups were higher than those of the sublingual and oral routes. Sublingual dosage interval should be less than this interval to get significant plasma levels. Lower vaginal delivery percentage in Feitossa et al.[43] study might be due to their higher dosage interval [6 hours Vs 4 hours]. So in our study we used 4 hours as repeat dosing interval.

Induction delivery interval measurement would have lot of bias because for cesarean section a team of doctors and paramedical staffs were required. There might be difference in duration for shifting the patient to operation theatre and administering anaesthesia. We had included that parameter in our study because there was no significant difference in number of caesarean section rate and indication for caesarean section among the groups.

Our study had showed a significant reduction in number of pelvic examination before delivery. Patient would be comfortable when number of pelvic examination was reduced. We had not taken satisfaction parameter in our study as it was beyond our scope. Nasser et al[8] had studied on patient satisfaction criteria and they had concluded that sublingual misoprostol was satisfactory route of administration than

vaginal route. This route of administration may reduce the chance of infection particularly in PROM cases because of less number of vaginal examinations required. On considering these facts and our observation on significant decrease in number of pelvic examination sublingual route may be a satisfactory route of administering misoprostol.

In our study there was no significant difference in mode of delivery. There was no significant difference in indication for caesarean delivery. It was similar to study conducted by Bartusevicius et al.[4] but they had used 50 μg of sublingual misoprostol. It showed that reduction of sublingual dosage from 50 μg to 25 μg had retained its effect on uterus without altering the mode of delivery and number of women delivered vaginally within 24 hours.

Different routes of misoprostol administration for labour induction necessitate carefully balancing the benefit (shorter time until delivery) against the risk (uterine hyperstimulation, adverse neonatal and maternal outcomes). Incidence of tachysystole {RR [CI 95%]-1 [0.34 -2.93]}, hypertonus {RR [CI 95%] -1 [0.06 – 15.62]} and hyperstimulation syndrome {RR [CI 95%]-1.5 [0.26 – 8.66]} was not significant in our study. In a recent study[4] where they had used 50 μg of sublingual misoprostol had noted three fold higher incidence of tachysystole in the sublingual than in the vaginal group. There were no significant differences between the two groups with respect to the number

of women experiencing hyperstimulation syndrome, or with regard to the mode of delivery or neonatal outcome, bearing in mind that their sample size was not powered to evaluate the parameters for safety. In our study we had observed no significant value for tachysystole with 25 μg of sublingual misoprostol, still we cannot conclude on adverse effect due to our sample size. Recent study had concluded that avoidance of a direct effect on the cervix did not reduce the risk of excessive uterine activity, as noted before but from our study reducing dosage can reduce this risk without compromising on our prime aim.

The neonatal outcomes were similar in both the trial groups. Comparable neonatal outcomes were noted in another study after 50 μg of misoprostol administered sublingually or vaginally. There was no significant difference in birth weight of baby [$p>0.05$] among the study groups. In term of other maternal complication, in our study patient had developed vomiting in two patients in each group. Misoprostol tablet as such had unpleasant taste. From our study, we found that vomiting can occur irrespective of route of administration. It might be due to systemic action of absorbed misoprostol. It needs large sample study to get inference for this complication. In view of the limited sample size of our study, we cannot reach definitive conclusions about the safety of sublingual misoprostol in this setting.

Sublingual dosing for labour induction is attractive because of ease of administration, less frequent need for vaginal examination, greater freedom of position and the possibility of its use despite vaginal bleeding or ruptured membranes. Cost of management was also low when comparing to other modes of induction. Even though this was not assessed in the present study, we assume higher patient acceptance of sublingual route, which was observed with oral when compared with vaginal administration.


Summary

SUMMARY

120 patients those for labour induction at term among whom 60 patients were administered 25 μg sublingual misoprostol every 4th hourly for maximum of 6 doses and remaining 60 patients were administered 25 μg vaginal misoprostol every 4th hourly for maximum of 6 doses were compared for efficacy and safety. Following outcome variables were measured and means between the groups were compared using an unpaired, two-tailed Student's *t* test. Categorical variables were analysed using chi-square test. $P < 0.05$ was considered statistically significant. For discrete data, relative risk (RR) with 95% confidence intervals (CI) was used.

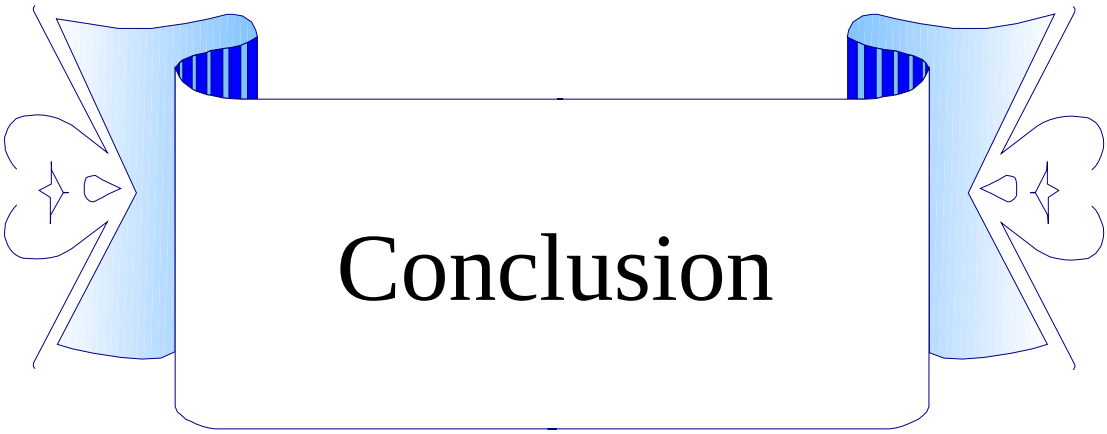
CRITERIA	SUBLINGUAL MISOPROSTOL n = 60	VAGINAL MISOPROSTOL n = 60	RELATIVE RISK[95% CI] OR P Value
Vaginal delivery <24 hours	52[86.7]	50[83.3]	1.04 [0.89 -1.20]
Total doses of misoprostol	1.85±1.02	2.3±1.2	P<0.05
Induction delivery interval (min)	650.98±250.83	779.7±269.97	P<0.05
Induction vaginal delivery interval (min)	597.42±186.47	720±195.47	P<0.005
Number of pelvic examination	5.75±2.05	8.22±2.04	P<0.05
Mode of delivery			
Spontaneous vaginal delivery	49[81.7]	45[75]	1.09 [0.90 – 1.32]
Instrumental vaginal delivery	3[5]	5[8.3]	0.6 [0.15 – 2.40]
Caesarean section	8[13.3]	10[16.7]	0.8 [0.34 -1.89]
Indication for caesarean delivery			
Fetal distress	2[25]	3[30]	0.83 [0.18 – 3.84]
Non progress of labour	4[50]	4[40]	1.25[0.45 – 3.49]
Failed induction	2[25]	3[30]	0.83 [0.18 – 3.84]
Oxytocin use	45[75]	47[78.3]	0.95 [0.79 – 1.17]
Tachysystole	6[10]	6[10]	1 [0.34 -2.93]
Hypertonus	1[1.7]	1[1.7]	1 [0.06 – 15.62]
Hyperstimulation syndrome	3[5]]	2[3.3]	1.5 [0.26 – 8.66]
Birth weight (kgs)	2.89±0.23	2.90±0.19	0.83
Apgar score < 7 at 5 minutes	2[3.3]	2[3.3]	1 [0.21 – 4.76]
Meconium passage	3[5]	3[5]	1 [0.15 – 6.87]
NICU admission	1[1.6]	2[3.3]	0.5 [0.05 – 5.37]
Maternal complication			
vomiting	2[3.3]	2[3.3]	1 [0.15 – 6.87]

Values as mean±SD, numbers[percentage]

Misoprostol used was significantly lower in sublingual route than vaginal route [$p<0.05$].

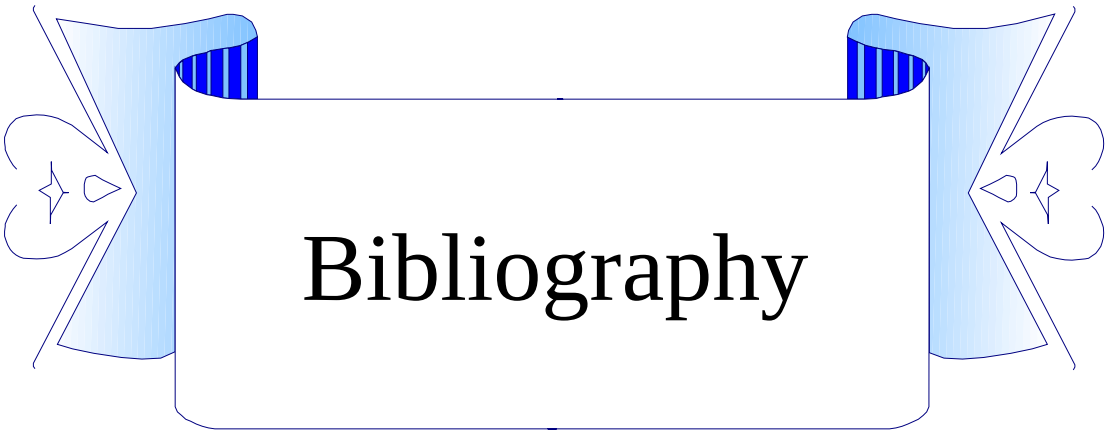
- Pelvic examination was significantly lower in sublingual route misoprostol than vaginal route of administration [$p<0.05$], thereby inconvenience caused by pelvic examination was less in sublingual route.
- Induction delivery interval including caesarean section and induction vaginal delivery interval was significantly lower in sublingual route misoprostol than vaginal route of administration [$p<0.05$].
- There was no significant difference among the groups in vaginal delivery in less than 24 hours.
- There was no significant difference among the groups in number [percentage] of patients where oxytocin was used in both groups
- There was no significant difference among the groups in number [percentage] of mode of delivery.
- There was no significant difference in fetal distress, non progress of labour / arrest of labour and failed induction among the groups.
- There was no significant difference among the groups in number [percentage] of maternal uterine complication.

- Two patient in each group developed vomiting.
- There was no significant difference among the groups in terms of meconium passage, Apgar score < 7 at 5 minutes and NICU admission.


Conclusion

CONCLUSION

we conclude that 25 μg of sublingual misoprostol administered every 4th hourly for maximum of 6 doses was more effective for induction in full term pregnancy than 25 μg of vaginal misoprostol administered every 4th hourly for maximum of 6 doses in terms of shortened induction delivery interval, less number of misoprostol tablets required and less number of pelvic examination required. It neither alter vaginal delivery rate and caesarean section rate nor produce significant complications like hypertonus, tachysystole and hyperstimulation syndrome than vaginal misoprostol route of administration. We believe further studies on safety with larger numbers of women need to be conducted before we advocate sublingual misoprostol as routine labour induction agent.



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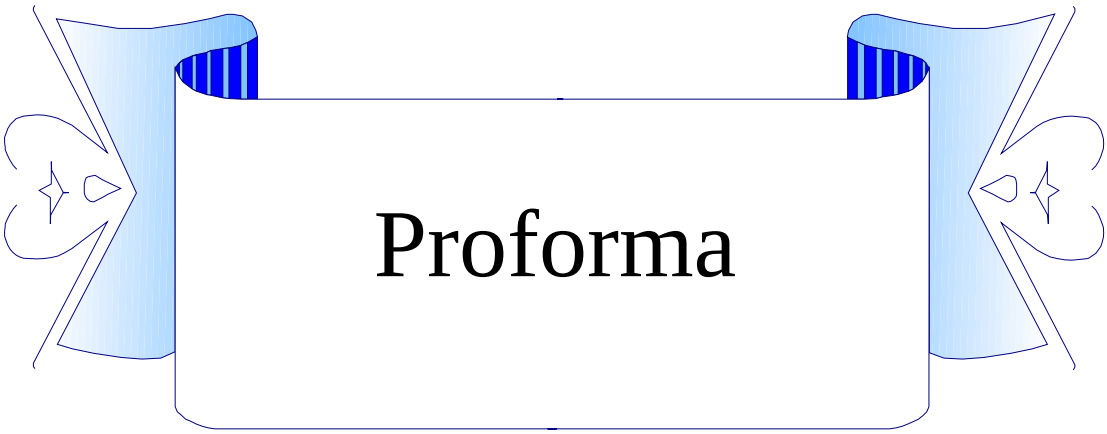

Proforma

PROFORMA

NAME: AGE: IP NO:

DOA: BOOKING STATUS: IMMUNISATION:

OBSTETRIC CODE: LMP: EDD:

MENSTURAL HISTORY:

PREVIOUS PREGNANCY OUTCOME:

PREGNANCY ASSOCIATED COMPLICATION:

- MATERNAL :
- FETAL :

MEDICAL DISEASE:

EXAMINATION

PALLOR/JAUNDICE/PEDAL EDEMA/FEBRILE

HEIGHT: WEIGHT : BMI :

PULSE : BP : RR : TEMPERATURE:

CVS :

RS :

P/A :

- Ø Uterus
- Ø Acting / not acting

- Head Engagement
- FH
- Liquor

P/V:

- Cervix Bishop Score:
  - Effacement
  - Dilatation
  - Position
  - Consistency
- Membrane
- Vertex station
- Pelvis
- Liquor draining: Y/N Colour of liquor:

INVESTIGATION:

- Hb
- Urine routine
- Blood grouping& typing
- USG GA: AFI:
- CTG

INDICATION FOR INDUCTION:

ROUTE OF ADMINISTRATION : SLM/VM

TIME AT THE START OF INDUCTION:

Number of misoprostol tablets	1	2	3	4	5	6
Time of administation						

OXYTOCIN USE: Y/N

MODE OF DELIVERY:

SVD IVD CS

Indication:

TIME OF DELIVERY:

INDUCTION DELIVERY INTERVAL:

NUMBER OF PELVIC EXAMINATION:

SIDE EFFECTS:

- MATERNAL:
  - Uterine tachysystole
  - Hypertonus
  - Hyper stimulation syndrome
  - Systemic

BABY:

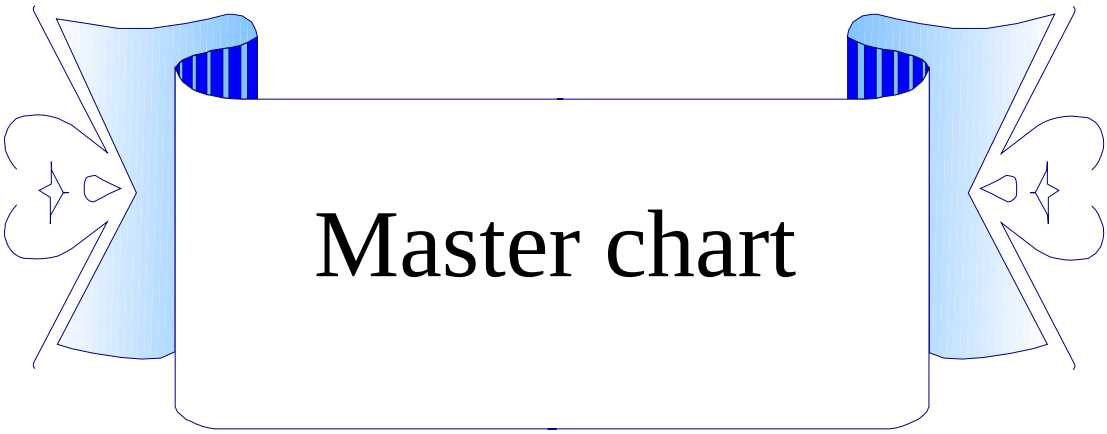
- Sex
- Birth weight
- Apgar score at 5 mins
- Meconium stained liquor
- NICU admission: Y/N Reason for admission:

COMPLICATION:

- Ø Intrapartum
- Ø Post partum
- Ø Neonatal

Date:

S. No :


Master chart

S. No.	NAME	AGE[YRS]	IP NUMBER	GRAVIDA	PARITY	GESTATIONAL AGE[WEEKS]	BISHOP SCORE	INDICATION FOR INDUCTION	STUDY GROUP	NOS OF MISOPROSTOL TABLETS	NOS OF PER VAGINAL EXAMINATION	OXYTOCIN USE	TACHYSYSTOLE	HYPERTONUS	HYPER STIMULATION SYNDROME	MODE OF DELIVERY	INDUCTION VAGINAL DELIVERY TIME[MINS]	INDUCTION DELIVERY TIME[MINS]	INDICATION FOR CAESEREAN SECTION	MATERNAL ADVERSE EFFECTS	BIRTH WEIGHT [KG]	MECONIUM STAINED LIQUOR	NICU ADMISSION	5 MIN APGAR SCORE
1.	Lakshmi	28	2588	P	1	41	3	PD	VM	6	13	N	N	N	N	CS	0	1564	FI	N	3.2	N	N	9
2.	Usha	20	8330	P	1	38	4	MPE	VM	2	7	Y	N	N	N	SVD	944	944	N	N	2.8	N	N	9
3.	Valarmathi	22	9502	P	1	38	3	PROM	VM	2	8	Y	N	N	N	SVD	670	670	N	N	2.7	N	N	9
4.	Amudham	18	10310	P	1	41	3	PD	VM	4	10	Y	N	N	N	SVD	1060	1060	N	N	3	MCL	N	9
5.	Muthulaxmi	23	10354	P	1	40	5	PROM	SLM	1	3	Y	N	N	N	SVD	324	324	N	N	2.9	N	N	9
6.	Manjula	24	10987	P	1	42	3	PD	SLM	3	9	Y	N	N	N	SVD	844	844	N	N	2.7	N	N	9
7.	Amutha	27	11225	P	1	37	5	PROM	SLM	1	4	N	Y	N	N	SVD	340	340	N	N	2.8	N	N	8
8.	Pappathi	27	12035	G2P1L1	2	38	3	PROM	SLM	3	10	Y	N	N	N	CS	0	944	NPL	N	2.8	N	N	8
9.	Praveena	23	12458	P	1	41	4	PD	SLM	2	6	Y	N	N	N	SVD	610	610	N	N	2.7	N	N	8
10.	Angurani	26	12546	G3P1L1A1	3	41	3	PD	SLM	2	7	Y	N	N	N	SVD	688	688	N	N	2.7	N	N	9
11.	Fairose	34	12784	G2P1L1	1	43	3	PD	SLM	3	8	N	N	N	N	SVD	790	790	N	N	2.6	N	N	8
12.	Lakna	19	13541	P	1	38	4	MPE	VM	2	8	Y	N	N	N	IVD	769	769	N	N	3.2	N	N	9
13.	Selvarani	28	13542	P	1	40	4	GDM	SLM	2	7	Y	N	N	N	CS	0	866	FD	N	2.7	N	N	9
14.	Lalitha	25	13547	P	1	38	5	PROM	SLM	1	4	Y	N	N	N	SVD	510	510	N	N	2.8	N	N	9

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15.	Rathnammal	26	14436	P	1	38	4	PROM	VM	2	6	N	N	N	N	SVD	692	692	N	N	2.6	N	N	9
16.	Govindamma	29	14578	G2P1L1	2	38	5	MPE	SLM	1	4	Y	N	N	N	SVD	415	415	N	N	2.9	N	N	8
17.	Rejula	20	15040	P	1	41	4	PD	SLM	1	4	Y	Y	N	Y	SVD	364	364	N	N	2.8	N	N	9
18.	Parimala	28	15069	G2P1L1	2	39	5	MPE	VM	1	8	Y	N	N	N	SVD	454	454	N	N	2.8	N	N	9
19.	Chellathaye	24	15088	P	1	41	4	PD	VM	2	8	Y	N	N	N	SVD	644	644	N	N	2.8	N	N	9
20.	Uma	26	15320	P	1	41	5	PROM	SLM	1	3	N	Y	N	N	SVD	810	810	N	N	3.2	N	N	9
21.	Sathya	21	15410	P	1	37	5	MPE	SLM	2	7	Y	N	N	N	SVD	744	744	N	N	3	N	N	9
22.	Padma	22	15478	P	1	41	4	PD	SLM	1	4	Y	N	N	N	SVD	310	310	N	N	2.6	N	N	9
23.	Nirmala	29	15512	P	1	41	4	PD	VM	2	7	Y	N	N	N	SVD	646	646	N	N	2.9	N	N	9
24.	Nirupa	31	15642	G3P1L1A1	3	41	4	PD	VM	2	7	Y	N	N	N	CS	0	788	FD	N	3	N	Y	6
25.	Thangam	29	15776	P	1	42	4	PD	VM	2	9	Y	N	N	N	SVD	890	890	N	N	2.9	N	N	9
26.	Valli	29	16372	G2P1L1	2	38	4	MPE	VM	2	9	Y	Y	N	Y	SVD	800	800	N	N	2.8	N	N	8
27.	Palaniammal	19	16420	P	1	40	4	PROM	SLM	1	4	Y	N	N	N	SVD	348	348	N	N	2.6	N	N	9
28.	Sumathi	27	16587	P	1	41	4	PD	SLM	2	8	Y	N	N	N	SVD	710	710	N	N	3.1	N	N	9
29.	Thangathai	30	16763	P	1	41	4	PD	VM	2	7	Y	N	N	N	SVD	988	988	N	N	2.7	N	N	9

S. No.	NAME	AGE[YRS]	IP NUMBER	GRAVIDA	PARITY	GESTATIONAL AGE[WEEKS]	BISHOP SCORE	INDICATION FOR INDUCTION	STUDY GROUP	NOS OF MISOPROSTOL TABLETS	NOS OF PER VAGINAL EXAMINATION	OXYTOCIN USE	TACHYSYSTOLE	HYPERTONUS	HYPER STIMULATION SYNDROME	MODE OF DELIVERY	INDUCTION VAGINAL DELIVERY TIME[MINS]	INDUCTION DELIVERY TIME[MINS]	INDICATION FOR CAESEREAN SECTION	MATERNAL ADVERSE EFFECTS	BIRTH WEIGHT [KG]	MECONIUM STAINED LIQUOR	NICU ADMISSION	5 MIN APGAR SCORE
30.	Aruldevi	22	17940	P	1	41	4	PD	VM	3	9	Y	N	N	N	SVD	890	890	N	N	3	N	N	8
31.	Akila	24	18185	P	1	38	5	MPE	VM	1	9	Y	N	N	N	SVD	322	322	N	N	2.8	N	N	9
32.	Maheshwari	18	18742	P	1	42	5	PD	SLM	1	4	Y	N	N	N	SVD	290	290	N	N	2.8	N	N	9
33.	Sathya	24	18927	P	1	39	4	PROM	VM	2	7	Y	N	N	N	SVD	688	688	N	N	3.1	N	N	9
34.	Parasakthi	25	20365	G2P1L1	2	37	4	MPE	SLM	1	4	Y	N	N	N	SVD	510	510	N	N	3	N	N	9
35.	Rajeshwari	29	20376	G2P1L1	2	41	4	PD	VM	2	7	Y	N	N	N	SVD	906	906	N	N	2.8	N	N	9
36.	Vanitha	29	20546	G2P1L1	2	37	4	PROM	VM	3	10	Y	Y	N	N	SVD	910	910	N	N	2.8	MSL	N	8
37.	Rathna	26	21032	P	1	42	4	PD	SLM	1	3	Y	N	N	N	SVD	432	432	N	N	3.4	N	N	9
38.	Suguna	28	21265	G2P1L1	2	38	4	GDM	VM	1	5	N	N	N	N	SVD	344	344	N	N	2.8	N	N	9
39.	Kalaimahal	28	21302	P	1	38	5	PROM	VM	3	11	N	N	N	N	SVD	845	845	N	N	2.9	N	N	9
40.	Rajamani	23	21356	P	1	42	4	PD	SLM	3	9	Y	Y	N	Y	SVD	986	986	N	N	2.9	MSL	N	8
41.	Prathiba	30	21382	G2P1L1	2	42	5	PD	SLM	2	6	Y	N	N	N	IVD	740	740	N	N	2.8	N	N	8
42.	Thangam	19	21400	P	1	37	3	PROM	SLM	2	6	Y	N	N	N	CS	0	840	NPL	N	2.6	N	N	8
43.	Raja rajeshwari	24	21456	G4P2L2A1	4	41	5	PD	SLM	1	4	N	Y	N	N	SVD	458	458	N	N	2.8	N	N	9
44.	Gracy	29	21458	P	1	40	4	GDM	SLM	2	7	Y	N	N	N	SVD	710	710	N	N	2.8	N	N	9

S. No.	NAME	AGE[YRS]	IP NUMBER	GRAVIDA	PARITY	GESTATIONAL AGE[WEEKS]	BISHOP SCORE	INDICATION FOR INDUCTION	STUDY GROUP	NOS OF MISOPROSTOL TABLETS	NOS OF PER VAGINAL EXAMINATION	OXYTOCIN USE	TACHYSYSTOLE	HYPERTONUS	HYPER STIMULATION SYNDROME	MODE OF DELIVERY	INDUCTION VAGINAL DELIVERY TIME[MINS]	INDUCTION DELIVERY TIME[MINS]	INDICATION FOR CAESEREAN SECTION	MATERNAL ADVERSE EFFECTS	BIRTH WEIGHT [KG]	MECONIUM STAINED LIQUOR	NICU ADMISSION	5 MIN APGAR SCORE
45.	Vijayalakshmi	24	21547	P	1	38	4	MPE	SLM	2	4	Y	N	N	N	SVD	720	720	N	N	2.5	N	N	9
46.	Maha	23	21636	P	1	39	4	MPE	VM	1	5	N	N	N	N	SVD	700	700	N	N	2.9	N	N	9
47.	Sujitha	21	22214	P	1	39	3	PROM	SLM	1	3	Y	N	N	N	IVD	554	554	N	N	3.4	N	N	8
48.	Juliet regina	23	22314	P	1	43	3	PD	SLM	3	9	Y	N	N	N	CS	0	967	NPL	N	2.6	N	N	8
49.	Suseela	21	22356	P	1	39	3	PROM	SLM	2	7	Y	N	N	N	SVD	654	654	N	N	2.8	N	N	9
50.	Radhika	23	22733	P	1	41	4	PD	VM	2	8	Y	N	N	N	SVD	688	688	N	N	3	N	N	8
51.	Anisha begum	26	23548	P	1	38	4	PROM	VM	2	9	Y	N	N	N	SVD	723	723	N	N	3.2	N	N	9
52.	Kalavathy	20	23564	P	1	42	2	PD	SLM	3	9	Y	N	N	N	SVD	824	824	N	VOM	3	N	N	9
53.	Suganya	25	24112	G2P1L1	2	41	4	PD	VM	2	7	Y	N	N	N	SVD	755	755	N	N	3.2	N	N	9
54.	Senmalar	28	24510	P	1	42	3	PD	SLM	6	7	N	N	N	N	CS	0	1466	FI	N	2.8	N	N	8
55.	Parameshwari	22	24781	P	1	38	3	MPE	VM	3	9	Y	N	N	N	SVD	896	896	N	N	2.6	N	N	9
56.	Saradha	20	24884	P	1	41	4	PD	VM	3	10	Y	N	N	N	SVD	1056	1056	N	VOM	2.6	N	N	9
57.	Jashitha	18	25108	P	1	42	4	PD	SLM	2	8	Y	N	N	N	CS	0	780	NPL	N	3	N	N	7
58.	Rathinam	28	25210	P	1	39	5	PROM	SLM	2	6	N	N	N	N	SVD	823	823	N	N	2.6	N	N	9
59.	Meenakshi	28	25462	P	1	42	4	PD	SLM	3	9	N	N	N	N	SVD	788	788	N	N	3.1	N	N	8

S. No.	NAME	AGE[YRS]	IP NUMBER	GRAVIDA	PARITY	GESTATIONAL AGE[WEEKS]	BISHOP SCORE	INDICATION FOR INDUCTION	STUDY GROUP	NOS OF MISOPROSTOL TABLETS	NOS OF PER VAGINAL EXAMINATION	OXYTOCIN USE	TACHYSYSTOLE	HYPERTONUS	HYPER STIMULATION SYNDROME	MODE OF DELIVERY	INDUCTION VAGINAL DELIVERY TIME[MINS]	INDUCTION DELIVERY TIME[MINS]	INDICATION FOR CAESEREAN SECTION	MATERNAL ADVERSE EFFECTS	BIRTH WEIGHT [KG]	MECONIUM STAINED LIQUOR	NICU ADMISSION	5 MIN APGAR SCORE
60.	Revathi	26	25467	P	1	37	3	GDM	SLM	2	8	Y	N	N	N	SVD	584	584	N	N	2.9	N	N	9
61.	Mallika	23	25472	P	1	41	5	PD	SLM	2	6	Y	N	N	N	SVD	463	463	N	N	2.7	N	N	9
62.	Kalyani	22	25478	P	1	37	2	MPE	SLM	2	7	Y	N	N	N	SVD	630	630	N	N	2.8	N	N	8
63.	Vinisha	21	25484	G2P1L1	2	38	4	PROM	VM	1	5	Y	N	N	N	SVD	566	566	N	N	2.7	N	N	9
64.	Ponni	28	25496	P	1	41	4	PD	VM	2	10	Y	N	N	N	SVD	802	802	N	N	2.8	N	N	9
65.	Akilandam	26	25564	G2P1L1	2	43	4	PD	SLM	2	8	Y	N	Y	Y	SVD	810	810	N	N	3	N	N	8
66.	Kamathchi	26	25616	P	1	38	4	MPE	VM	3	9	Y	N	N	N	IVD	900	900	N	N	3.2	N	N	8
67.	Anifa	35	25674	G2P1L1	2	40	5	GDM	SLM	2	7	Y	N	N	N	SVD	682	682	N	N	3	N	N	9
68.	Karaimathi	22	25689	G3P2L2	3	38	3	MPE	SLM	2	6	N	N	N	N	SVD	732	732	N	N	2.8	N	N	8
69.	Sivakami	31	25698	G2P1L1	2	40	4	PROM	SLM	1	3	N	N	N	N	SVD	768	768	N	N	3	N	N	9
70.	Vinitha	23	25714	P	1	37	5	MPE	SLM	2	8	Y	N	N	N	SVD	684	684	N	N	2.8	N	N	9
71.	Annie mathew	31	25848	G2P1L1	2	41	5	PD	VM	2	8	Y	N	N	N	SVD	890	890	N	N	2.6	N	N	9
72.	Mayil	22	26651	P	1	42	5	PD	SLM	2	7	Y	N	N	N	SVD	744	744	N	N	3.2	N	N	8
73.	Aiyyamal	25	27458	G2P1L1	2	42	4	PD	SLM	1	3	Y	Y	N	N	SVD	324	324	N	N	3	MSL	N	9
74.	Senbagam	24	27951	P	1	38	3	PROM	VM	6	13	N	N	N	N	CS	0	1500	FI	N	3.4	N	N	9

S. No.	NAME	AGE[YRS]	IP NUMBER	GRAVIDA	PARITY	GESTATIONAL AGE[WEEKS]	BISHOP SCORE	INDICATION FOR INDUCTION	STUDY GROUP	NOS OF MISOPROSTOL TABLETS	NOS OF PER VAGINAL EXAMINATION	OXYTOCIN USE	TACHYSYSTOLE	HYPERTONUS	HYPER STIMULATION SYNDROME	MODE OF DELIVERY	INDUCTION VAGINAL DELIVERY TIME[MINS]	INDUCTION DELIVERY TIME[MINS]	INDICATION FOR CAESEREAN SECTION	MATERNAL ADVERSE EFFECTS	BIRTH WEIGHT [KG]	MECONIUM STAINED LIQUOR	NICU ADMISSION	5 MIN APGAR SCORE
75.	Priya	22	31589	P	1	38	5	GDM	VM	2	8	Y	N	N	N	SVD	788	788	N	N	2.8	N	N	9
76.	Vijayarani	35	31699	G2P1L1	2	41	3	PD	VM	2	8	Y	N	N	N	SVD	932	932	N	N	2.9	N	N	9
77.	Manjula	28	32293	P	1	40	4	PROM	VM	6	13	N	N	N	N	CS	0	1490	FI	N	3	N	N	9
78.	Shahira	30	32312	P	1	41	4	PD	SLM	2	6	Y	N	N	N	SVD	621	621	N	N	3.2	N	N	9
79.	Shantha kumari	32	32460	G3P1L1A1	3	41	4	PD	SLM	1	4	Y	N	N	N	SVD	310	310	N	N	2.8	N	N	9
80.	Elaiyammal	28	32541	P	1	37	4	MPE	SLM	2	8	Y	N	N	N	SVD	742	742	N	N	3.4	N	N	9
81.	Vijaya	21	32546	P	1	41	4	PD	VM	3	9	Y	Y	N	N	SVD	910	910	N	N	3	N	N	9
82.	Thennai valli	35	32550	G2P1L1	2	40	4	PROM	SLM	1	4	Y	N	N	N	CS	0	566	FD	N	3.4	N	Y	6
83.	Sathya priya	24	32552	P	1	41	4	PD	SLM	2	6	Y	N	N	N	SVD	942	942	N	N	2.9	N	N	9
84.	Karpagam	25	32560	P	1	41	4	PD	SLM	2	6	Y	N	N	N	SVD	654	654	N	N	3.2	N	N	9
85.	Savithri	27	32564	P	1	37	5	MPE	SLM	1	4	N	N	N	N	SVD	354	354	N	N	2.9	N	N	9
86.	Cheela kaur	22	32566	P	1	42	4	PD	SLM	6	6	Y	N	N	N	CS	0	1564	FI	N	2.7	N	N	9
87.	Banumathy	26	32568	G2P1L1	2	38	5	PROM	SLM	1	3	N	N	N	N	SVD	486	486	N	N	2.9	N	N	8
88.	Arokiya	24	34561	P	1	39	4	PROM	VM	2	8	Y	N	N	N	SVD	890	890	N	N	2.8	N	N	8
89.	Yashmin banu	22	35447	P	1	38	4	PROM	SLM	2	4	N	N	N	N	SVD	400	400	N	VOM	3	N	N	8

S. No.	NAME	AGE[YRS]	IP NUMBER	GRAVIDA	PARITY	GESTATIONAL AGE[WEEKS]	BISHOP SCORE	INDICATION FOR INDUCTION	STUDY GROUP	NOS OF MISOPROSTOL TABLETS	NOS OF PER VAGINAL EXAMINATION	OXYTOCIN USE	TACHYSYSTOLE	HYPERTONUS	HYPER STIMULATION SYNDROME	MODE OF DELIVERY	INDUCTION VAGINAL DELIVERY TIME[MINS]	INDUCTION DELIVERY TIME[MINS]	INDICATION FOR CAESEREAN SECTION	MATERNAL ADVERSE EFFECTS	BIRTH WEIGHT [KG]	MECONIUM STAINED LIQUOR	NICU ADMISSION	5 MIN APGAR SCORE
90.	Logeshwari	25	35624	P	1	37	4	MPE	SLM	2	8	Y	N	N	N	SVD	748	748	N	N	2.8	N	N	9
91.	Vasantha rubini	20	36985	P	1	41	4	PD	SLM	2	7	Y	N	N	N	SVD	684	684	N	N	3.1	N	N	8
92.	Rosemary	26	37321	P	1	41	5	PD	VM	2	8	Y	N	N	N	SVD	806	806	N	N	2.8	N	N	8
93.	Veerayee	21	38100	P	1	39	4	PROM	VM	3	11	Y	N	N	N	CS	0	832	NPL	N	2.8	N	N	9
94.	Mala	28	38971	G3P2L2	3	40	4	PROM	SLM	1	5	Y	N	N	N	SVD	422	422	N	N	3.3	MSL	N	9
95.	Sarasu	28	39452	G2P1L1	2	37	4	MPE	VM	1	5	Y	N	N	N	SVD	466	466	N	N	2.7	N	N	9
96.	Vasuki	20	41256	P	1	40	5	PROM	SLM	1	3	N	N	N	N	SVD	522	522	N	N	2.5	N	N	8
97.	Neelavathi	31	41470	G3P2P2	3	37	5	PROM	VM	1	4	N	N	N	N	IVD	639	639	N	N	2.9	N	N	9
98.	Kasambu	26	42071	G2P1L0	2	38	5	PROM	VM	2	8	Y	N	N	N	CS	0	844	NPL	N	3.4	N	N	9
99.	Lakshmi	25	44163	G2P1L1	2	41	5	PD	VM	1	6	Y	N	N	N	IVD	340	340	N	N	2.8	N	N	9
100.	Sultana	24	45682	P	1	38	3	PROM	VM	2	9	Y	Y	N	N	SVD	688	688	N	N	3.1	N	N	8
101.	Devi chitra	26	45784	P	1	40	4	PROM	SLM	1	3	N	N	N	N	SVD	650	650	N	N	2.6	N	N	9
102.	Hairunisha	31	46058	P	1	38	4	PROM	VM	2	8	Y	N	N	N	SVD	543	543	N	VOM	2.8	N	N	9
103.	Kokila	26	49630	P	1	38	5	GDM	VM	2	9	N	N	N	N	CS	0	644	FD	N	2.7	MSL	Y	7
104.	Sellarani	24	49942	P	1	41	4	PD	VM	3	8	Y	Y	N	N	SVD	784	784	N	N	2.9	N	N	9

S. No.	NAME	AGE[YRS]	IP NUMBER	GRAVIDA	PARITY	GESTATIONAL AGE[WEEKS]	BISHOP SCORE	INDICATION FOR INDUCTION	STUDY GROUP	NOS OF MISOPROSTOL TABLETS	NOS OF PER VAGINAL EXAMINATION	OXYTOCIN USE	TACHYSYSTOLE	HYPERTONUS	HYPER STIMULATION SYNDROME	MODE OF DELIVERY	INDUCTION VAGINAL DELIVERY TIME[MINS]	INDUCTION DELIVERY TIME[MINS]	INDICATION FOR CAESEREAN SECTION	MATERNAL ADVERSE EFFECTS	BIRTH WEIGHT [KG]	MECONIUM STAINED LIQUOR	NICU ADMISSION	5 MIN APGAR SCORE
105.	Kalaiselvi	26	50442	G3P2L1	3	37	4	MPE	VM	1	5	N	N	N	N	SVD	324	324	N	N	3	N	N	9
106.	Pappathi	24	51548	P	1	38	4	MPE	VM	2	9	Y	N	N	N	SVD	568	568	N	N	3	N	N	9
107.	Poomani	21	51872	P	1	41	3	PD	VM	6	13	N	N	N	N	CS	0	1540	FI	N	2.8	N	N	9
108.	Thilagavathy	22	52004	P	1	38	4	PROM	VM	2	9	Y	N	N	N	SVD	655	655	N	N	3.2	N	N	9
109.	Lalitha	20	53134	P	1	41	4	PD	VM	3	7	N	N	N	N	SVD	866	866	N	N	2.8	N	N	9
110.	Rajeshwari	19	53868	P	1	38	4	PROM	VM	1	5	Y	N	N	N	SVD	432	432	N	N	3.1	N	N	8
111.	Vishi begum	24	54215	P	1	38	4	MPE	VM	2	9	N	N	N	N	SVD	810	810	N	N	2.7	N	N	9
112.	Rahmath	25	54551	P	1	41	3	PD	VM	2	9	Y	Y	N	Y	IVD	644	644	N	N	2.8	N	N	9
113.	Arokiaya mary	23	54621	P	1	38	5	MPE	VM	3	9	Y	N	N	N	CS	0	844	NPL	N	2.8	N	N	9
114.	Noorjahan	29	54626	P	1	41	4	PD	VM	2	8	Y	N	N	N	CS	0	730	NPL	N	2.8	N	N	8
115.	Banupriya	23	55410	G2P1L1	2	42	4	PD	VM	2	10	Y	N	N	N	SVD	744	744	N	N	2.6	N	N	9
116.	Tamilselvi	28	57376	P	1	41	4	PD	VM	2	8	Y	N	Y	N	SVD	453	453	N	N	3.1	N	N	9
117.	Vellamal	22	57986	P	1	38	5	PROM	VM	1	5	Y	N	N	N	SVD	420	420	N	N	2.9	N	N	9
118.	Sangeetha	27	59320	G3P2L1	3	38	3	PD	SLM	1	3	Y	N	N	N	SVD	490	490	N	N	2.8	N	N	9
119.	Annama	21	65842	P	1	37	4	MPE	VM	2	7	Y	N	N	N	SVD	866	866	N	N	3	N	N	9
120.	Akila	26	65868	G2P1L1	2	38	4	MPE	SLM	1	5	N	N	N	N	SVD	284	284	N	N	2.8	N	N	9

ABBREVIATIONS

IP number	Inpatient number
G_n P_n L_n A_n	Gravida, para, live birth, abortion. n – Number
PD	Post dated
MPE	Mild pre eclampsia
PROM	Prelabor rupture of membrance
GDM	Gestational diabetic mellitus
SLM	Sublingual misoprostol
VM	Vaginal misoprostol
Y,N	Yes, No
SVD	Spontaneous vaginal delivery
IVD	Instrumental vaginal delivery
CS	Caesarean section
NPL	Non progress of labour
FD	Fetal distress
FI	Failed Induction

VOM	Vomiting
MSL	Meconium stained liquor
MINS	Minutes
KGS	Kilograms
YRS	Years
RR	Relative risk
CI	Confidence interval
NICU	Neonatal intensive care unit
µg	Microgram
CTG	Cardiotocography
IUD	Intrauterine Fetal Death
FHR	Fetal Heart Rate
GA	Gestational Age
BP	Blood Pressure